Irritable Bowel Syndrome with Constipation (IBS-C) Treatment Efficacy and the Emerging Importance of Serotonin

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Irritable Bowel Syndrome with Constipation (IBS-C) Treatment

Efficacy and the Emerging Importance of Serotonin

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Appendix A
Irritable Bowel Syndrome with Constipation

Abstract

Irritable bowel syndrome with constipation (IBS-C) affects a large proportion of the population. It decreases quality of life for the patient both physically and mentally. Patients report higher levels of mental health issues and other gastrointestinal maladies compared to the normal population, in addition to an IBS diagnosis. Patients have increased healthcare visits and costs, raising insurance rates for all, and also results in more missed time from work. There are limited treatments available for IBS-C, and medicinal and non-medicinal modalities are differentially prescribed to patients throughout the country. Recently, serotonin has emerged as a key mediator of normal gut function, and thus, of IBS dysfunction. This chemical is implicated in physiological processes throughout the body, and serves as a key focus of IBS treatment. Current knowledge of IBS-C, treatments, and differences in care plans based on geography are explored in this review.

One sentence summary: This review explores the most recent etiology, treatment, and differences in care for IBS-C.
Irritable bowel syndrome (IBS) affects around ten percent of the national population (1). Patients affected by IBS generally have a decreased quality of life and need to frequently utilize healthcare services (1). The estimated cost to the healthcare system from IBS patients is around $10 billion dollars, and the mechanism of IBS development remains unknown making treatment more difficult (1, 2). There are three recognized variations of IBS. IBS-D is marked by frequent diarrhea. IBS-C is marked by prevalent constipation. IBS-M is more rare and is a mixture of diarrhea and constipation. (1). IBS-D has more effective treatment modalities and has been studied more heavily than IBS-C (1). IBS-C has few treatments and relatively low efficacy of treatment, so this review will focus on IBS-C, as it is more poorly understood.

Methods

PubMed, Academic Search Premier, and Elsevier databases were used to find the most relevant research. The search terms used were IBS-C, irritable bowel syndrome with constipation. Treatment, causes, serotonin, and etiology were used with the primary search terms as well. Databases were search for 10 months.

Treatment of IBS-C

Treatment of IBS-C is individualized for the patient. Symptoms can vary between patients, but they usually include infrequent bowel movements, cramping, nausea, abdominal pain, weight loss, and bloating (1). A patient’s primary care physician or gastroenterologist usually determines treatment. There is not a standard treatment for IBS-C, so treatment can vary greatly between patients. Although many treatments exist, there is not room to discuss all modalities. Most frequently used modalities will be discussed in non-medicinal and medicinal groups.
Non-Medicinal Treatment

Although there are many non-medicinal treatments for IBS-C the most used and researched interventions are diet and lifestyle changes (3). To begin, dietary changes are frequently attempted by IBS patients. Many patients have ‘trigger’ foods that greatly increase their symptoms (1,2,3). Often dietary changes are a priority in IBS-C treatment.

Low FODMAP diets have been shown to decrease symptoms in compliant patients (3). FODMAPs are fermentable oligosaccharides, disaccharides, monosaccharaides, and plynos (3). When compared to a western diet, a low FODMAP diet reduced IBS symptoms by 22.8% with a 95% confidence interval (3). However, fecal consistency did not change for IBS-C patients indicating that treatment helps, but is not sufficient for IBS-C treatment (3).

In addition to dietary changes, lifestyle changes such as exercise can improve IBS-C symptoms. Yoga in particular is an effective exercise treatment method (4). When Yoga was added to the treatment plan, adolescents with IBS reported less functional disability from IBS-C and an increased ability to control their emotions (4).

Probiotics are also used to improve IBS-C symptoms. When compared to probiotic free diets, 82.5% patients had higher overall digestive comfort (5).
Interestingly, the quantity of probiotics ingested over one serving did not significantly increase the percentage of patients reporting improved symptoms (5).

Overall, non-medicinal treatments can improve symptoms in patients, but are not effective enough to be used as a sole treatment. There are many more non-medicinal treatments than those mentioned above. However, most patients will require additional medicinal care, so only a few of the most common additions were mentioned.

**Medicinal IBS-C Treatment**

Two primary medications are used to increase bowel movements for IBS-C patients. One is linaclotide, common name Linzess, which has high evidence quality (6). Linaclotide works by increasing cGMP levels by mimicking guanylin in the gut (6). It opens chloride channels and causes colonic transit. The main side effect of linaclotide is diarrhea (6). The other medication is plecanatide, common name Trulance, which has just recently been approved for treatment (2). Plecanatide is a C-GMP agonist. It is similar to uroguanylin and increases cGMP in the intestine (6). Effects and mechanisms of the two drugs are quite similar (2,6). Medicinal treatment for IBS-C can be very expensive for the patient. After insurance, these medications still can cost patients around $300 dollars a month (6). Clearly, treatment for IBS-C is needed and these medicines offer symptom improvement for patients, however, the cost is prohibitive to care. Additionally, most patients will need to take these medicines every day for the rest of their lives.

Guanylin and uroguanylin are naturally secreted in the gut to aid digestion in healthy individuals (7). IBS-C patients tend to have lower than normal signaling through these proteins (7). The proteins affect digestion by increasing cGMP. The cGMP then interact with enterocytes to increase chloride secretion on the luminal membrane (2,6,7).
Interestingly, the proteins are pH dependent (7). Thus, their activity only functions in specific areas of the gut due to pH differences. Uroguanylin works at a more acidic pH, around 5, and guanylin is most effective at a pH of 8 (7). Guanylin exerts its effects in the jejunum whereas uroguanylin works in the duodenum (7). Thus, the two medications work on different areas of the small intestine making them exert similar but different effects for different patients (7). Increased chloride in the duodenum increases water retention in the small intestine. This maintains more water in the fecal matter making it easier to pass and helping relieve constipation. Plecanatide’s use of uroguanylin decreases dehydration side effects because the fecal matter still travels the entirety of the small intestine where 80% of water absorption occurs (7). Guanylin, has high levels of diarrhea as a side effect because it exerts its effects much later in the small intestine (7). Thus, guanylin has a slightly higher efficacy for constipation relief, but exerts more dangerous side effects on the patient like dehydration (7).

Another type of medication used for IBS-C treatment is an antispasmodic (8). However, this medication is used to treat symptoms of IBS-C for the patient rather than improve the etiology (8). Antispasmodics, such as Alverine, relax the smooth muscle in the small intestine (8). This helps patients alleviate symptoms such as intense cramping after a meal by reducing the intensity of contractions from their intestine (8). This treatment can help reduce the abdominal pain and discomfort associated with IBS-C.

Finally, the last class of drugs used for medicinal treatment is selective serotonin reuptake inhibitors (SSRIs) (9). SSRIs are typically used for treatment of depression; however, they have profound effects on IBS-C symptoms as well. Non-depressed IBS-C patients treated with SSRIs improved both symptoms of IBS-C and bowel movement
frequency (9). Abdominal pain, bloating, and general symptoms improved significantly (9). Bowel movement frequency improved as well, but more modestly. SSRIs improve symptoms of IBS-C patients, but also sensorimotor function of the colon (9).

![Graph](image)

**Figure 2.** Selective Serotonin Reuptake Inhibitors improve symptoms and colonic transit in IBS-C patients. Tack et al. *Gut.* 2006.

**Microbiota and IBS-C**

As previously stated, IBS-C is relatively poorly understood. An emerging subset of research within IBS-C is the microbiome’s contribution to the etiology. Breath tests can be used to diagnose bacterial overgrowths, but the test is only functional for aerobic bacteria (10,11,12). Anaerobic bacteria colonize the majority of the intestine, and the normal composition of human microbiomes is still being discovered. Thus, much of the research on this topic is subject to change, and often has conflicting results. However, dybiosis within the microbome of IBS-C patients has been categorized (10,11,12).

A study in France compared 14 IBS-C patients with 12 healthy volunteers. The study was limited due to it’s small size, but is important as the microbiome is just
beginning to be understood (10). Diets were not changed during the study and yogurts and all other probiotic products were avoided during microbiome testing (10). Fecal samples were collected and cultured, and total number of microbes did not differ between control and test subjects (10). The population of enterobacteriaceae was 10 fold higher in IBS-C patients compared to the control group with a p value of 0.0107 (10). Another main difference was found in bacteria involved in lactate metabolism. Lactic acid bacteria were lower in IBS-C patients with p<0.01 (10). Lactobacilli, bifidobacteria, and lactate-utilizing bacteria were all 10 fold lower than control populations (10). This may explain why lactose containing foods are a trigger for many patients.

Another study on rats with human microbiota found that IBS-C induced animals had higher Enterobacteriaceae, Desulfovibrio, and A. muciniphila (12). The researchers then were interested if A. muciniphila was enriched in human IBS-C patients as well. They found that it was enriched 20 fold with a P<0.01 compared to healthy patients (12) This indicated another component in IBS-C dysbiosis (12). Although many studies have been completed on IBS microbiome composition, studies on IBS-C specifically are rare and have small numbers of participants. Thus, the results from these studies are helpful for understanding the functional difference between IBS-C patients and healthy patients; however, many more studies are necessary to fully conclude the ‘normal’ dysbiosis characteristics of an IBS-C patient.

The role of microbiome dysbiosis with inflammation in IBS-C is strongly contested. A study of 20 IBS-C patients found increased IL-10 when Bifidobacterium and Lactobacillus were increased (11). However, as previously mentioned, IBS-C patients have lower numbers of these two bacteria. This may suggest that the body reacts to
increased population of these bacteria in the microbiome causing inflammation \( (11) \). The inflammation causes gut irritation and the immune system then lowers those populations of bacteria causing the lower population of those bacteria over longer periods of time \( (11) \).

Figure 3. Rats with human IBS-C microbiota release less inflammatory transcripts compared to rats with human normal microbiota when exposed to DSS. Shukla et al. JNM. 2018,

Another study found somewhat conflicting results. Rats with human microbiota from IBS-C and healthy patients were given DSS to induce colitis \( (12) \). Interestingly, normal microbiota rats had more edema, crypt abscesses, and congestion of the lamina propria compared to rats with IBS-C microbiota \( (12) \). Transcripts of pro-inflammatory genes in normal microbiota rats were higher across all transcripts compared to the IBS-C
microbiota group (12). This suggests that IBS-C patients actually have less inflammation response compared to healthy individuals. The study found that *A. muciniphila* was the likely bacteria protecting IBS-C rats from inflammation (12). The microbiome will likely be a large component of treatment of IBS-C in the future. For now, however, information is new and often times conflicts with other research. The microbiome will require much more study before treatment can be implemented with IBS-C, however, it is a very promising field that has many researchers, physicians, and patients hopeful.

**Small Intestine Function**

The main function of the small intestine is digestion, and motility and fluid secretion help the small intestine effectively break down nutrients. Mechanical stimulation is a large factor for proper secretion. Mechanical stimulation of the mucosa releases serotonin, which is a key mediator in effective secretion for digestion (13). Ninety-five percent of serotonin in the body is found in the gut (13). Additionally, ninety percent of gut serotonin is found in enterochromaffin cells (13). Serotonin then further orchestrates fluid secretion and motility. One important area of change from serotonin is an increase in chloride ion channels (14). Chloride channels increase water retention and secretion into the lumen of the small intestine (14). The amount of water in the small intestine determines the consistency of stool. Too much water results in diarrhea and too little results in constipation. Enterochromaffin cells are the main source of serotonin (5-HT) in the small intestine (15). However, mechanical stimulation of enterochromafin cells does not produce serotonin to expected levels (15). Piezo2 is a calcium ion channel protein that is also necessary for full serotonin release (15).
Piezo2 is present on about 75% of enterochromafin cells indicating that mechanical stimulation is sufficient for serotonin release, but for large spikes during digestion enterochromafin cells use Piezo2 to quickly increase secretion and motility within the small intestine (15). Additionally, Piezo2 channels are localized to the membrane and are functionally close to serotonin vesicles indicating functional coupling (14,15). All epithelial cells in the gut express serotonin selective reuptake transporters (15). This system of quick release and reuptake allows serotonin signaling to be tightly regulated within the small intestine making serotonin a primary mechanism to respond to the intrinsic and extrinsic environment (15).

**Figure 4.** Piezo2 protein is necessary for full serotonin release in the gut. Alcaino et al. PNAS 2018.

**Figure 5.** Serotonin signaling in enterochromafin cells (blue) and serotonin selective reuptake transporters in epithelial cells (red). Alcaino et al. PNAS 2018.
Enterochromafin cells also use chemosensing to modulate digestion by sensing noxious chemicals, metabolites and catecholamines (16). Interestingly, detection of all three of these categories results in increased serotonin release (16). Metabolites indicate that increased secretion and motility are needed for digestion, and serotonin begins that process (16). Catecholamines begin sympathetic nervous system activation, so serotonin secretion modulates sensory nerves and synaptic connections in this case rather than digestion (17). This system helps the gut brain axis respond to the environment quickly during stress to the body (16,17). Noxious chemicals indicate there is inflammation in the small intestine, and serotonin aids in signaling through sensory nerves through serotonin receptors to signal damage in the small intestine (16,17). Enterochromafin cells are polymodal chemosensors, which allows the gut brain axis to integrate extrinsic and intrinsic signals (16). It also highlights how integral serotonin signaling to proper small intestine function for both mechanosensitive and chemosensitive pathways (16). Serotonin produces excitatory postsynaptic potentials in enteric neurons (18). This helps control contraction and relaxation of the gut, regulating peristalsis (18). When acting on inhibitory nitrergic neurons, serotonin causes small bowel relaxation (18). However, when interacting with cholinergic receptors serotonin causes contraction (18). This duality further illustrates the complexity of serotonin signaling for digestion, and how small disruptions in serotonin homeostasis can cause a variety of symptoms and effects in patients.

**Serotonin and IBS-C**

As serotonin signaling is important for both secretion and motility, serotonin signaling should fluctuate in a healthy person as they eat and digest (19). Normally
concentration of serotonin should be about 21 nmol/L when fasting, 28.5 nmol/L when fed, and peak at 64.6 nmol/L during digestion (19). Interestingly, in IBS-C patients serotonin concentrations remain around 22 nmol/L throughout fasting, eating, and digestion (19). IBS-C patients do not experience the serotonin peak that healthy individuals have. This further influences digestive signaling throughout the body indicating that downstream serotonin signaling for secretion and motility are likely affected in IBS-C patients (19).

![Figure 6](image_url)

**Figure 6.** Serotonin signaling in normal patients (triangle), IBS-D patients (circle), and IBS-C patients (square). IBS-C patients serotonin concentrations are not affected by a meal. Atkinson et al. *Gastroenterology* 2006.

5-HIAA concentrations reflect the activity of monoamine oxidase (18). This helps measure serotonin turnover and metabolism (18). IBS-C patients also have lower concentrations of postprandial 5-HIAA (18) Interestingly, the ratio of 5-HT and 5-HIAA is comparable to healthy individuals in IBS-C (19). Finally, IBS-C patients have higher serotonin levels in the mucosa than IBS-D and healthy patients (18). This indicates that
the enterochromaffin cells are producing the serotonin, but not exocytosing it \((18,19)\). These results together indicate that IBS-C has reduced enterochromafin cell release of serotonin \((18,19)\). This data is interesting, but does not point to serotonin release as the sole cause of IBS-C. However, it does heavily implicate serotonin in symptom management for IBS-C patients \((14,18,19)\).

**Treatment with Serotonin**

Serotonin’s importance in small intestine signaling makes it a likely candidate for IBS-C treatment. Results are promising, but many trials have a mixed selection of IBS-C and IBS-D patients. These studies assume the two have similar etiologies, and that has not been proven yet. For the sake of clarity, only studies with IBS-C only patients are included.

Two types of medicines are used for serotonin modification in IBS-C patients, selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants \((20)\). SSRIs work by blocking reuptake of serotonin in neuronal synapses \((20)\). This mechanism keeps serotonin in the synapse longer so it can effectively perform its action by binding to receptors \((20)\). In reference to IBS-C, SSRIs would allow the small amounts of secreted serotonin to all successfully bind to receptors. Tricyclic antidepressants’ mechanism is similar for serotonin \((20)\). However, they also block norepinephrine reuptake and block the action of acetylcholine \((20)\).

SSRIs have shown efficacy in reducing global symptoms for IBS-C patients \((21,22,23)\). When 44 patients treated with fluoxetine for 12 weeks, abdominal discomfort and sense of bloating significantly decreased in patients as compared to the placebo group \((21)\). Additionally, frequency of bowel movements increased \((21)\). Symptoms in
the placebo group went from 4.5-2.9 (21). However, in the fluoxetine group symptoms went from 4.6-0.7 showing a benefit in treatment (21).

Citalopram, another SSRI, has also shown promising results in short-term double blind trials of six weeks of treatment (22). Again, abdominal pain and bloating decreased while stool pattern had only a modest change in this study (22). Interestingly, changes in depression or anxiety were not correlated with symptom improvement (22). This indicates that changes were due to serotonin signaling in the gut rather than improvement of mental health (22).

Paroxetine is another SSRI with promise. A study where the placebo was a high fiber diet and paroxetine was given in conjunction with a high fiber diet showed better results with paroxetine treatment (23). 26% of patients experienced symptom improvement from the high fiber diet alone (23). However, 63.3% of patients taking paroxetine as well as a high fiber diet experienced symptom improvement (23). This indicates that the drug improved symptoms more than just diet change alone.

Tricyclic antidepressants also show symptom improvement for IBS-C patients (24). Nine studies were compared Tegaserod improved symptoms significantly more than placebo (24). It relieved abdominal pain, bloating and constipation in patients (24). Tricyclic antidepressants had high drop out levels though (24). Patients were unable or unwilling to continue treatment. However, 1 our of 4 continued treatment after the trial because of the benefit they received (24). Thus, tricyclic antidepressants can be helpful, but are specific to patients and will not work for everyone.
Impact and Burden of IBS-C

IBS-C alone is difficult for the patient, but many IBS-C patients have symptom overlap with other functional disorders (25). 328 patients with IBS-C were checked for symptoms of other functional disorders and 271 (82.6%) of the patients had condition overlap (25). Demographics in this study were adjusted from the full sample to match demographics of the overall population (25).

![Diagram showing symptom overlap](image)

Figure 8. Patients with IBS-C have significant overlap with other functional disorders. Vakil et al. Gastroenterology 2016.

Additionally, the frequency of symptoms were significantly higher in IBS-C overlap groups compared with single-condition groups (26). Indicating that patients with overlap are more frequently affected by the conditions (26). This trend followed for all types of symptoms of IBS-C (26). Symptom bothersomeness was also increased in symptom overlap groups, further increasing the burden on patients (26). Finally, patients with symptom overlap were more likely to consult a physician than those with one functional disorder (26). GERD, functional disorder, and IBS-C are more likely to
overlap than other functional disorders (26). A third of patients with IBS-C will also have a diagnosis of GERD or functional disorder or both (26).

In addition to the burden of symptoms, IBS-C patients are also not usually satisfied with the relief from their care (27). Out of 557 respondents, 52% said that their symptoms reduced their quality of life and 12% believe their productivity was negatively impacted by symptoms (27). Nearly all, 96%, had or currently needed constipation therapy to combat their symptoms in addition to other medications (27). Finally, 47% were not satisfied with the efficacy of their treatment (27). A similar study with 1311 respondents found similar statistics for symptoms and quality of life (28). Interestingly, 40% of participants in this study also indicated that they had accepted IBS-C as a permanent part of daily life (28). Indicating that they had given up hope of curing their symptoms.

Although the physical effects of IBS are significant, the economic effects warrant mention as well. IBS-C patients are more likely to take days off work because of their symptoms (29). Additionally, they have reduced activities and involvement compared to non-sufferers (29). When direct medical costs are compared for IBS-C patients and control patients, IBS-C patients are understandably higher. 4,527 dollars were spent in 1998 compared to $3,276 for a control beneficiary (30). Additionally, outpatient care costs were $1,258 and $742 for patients with IBS and controls respectively (30). Indirect costs were also affected. Patients with IBS cost employers $901 dollars on average from missing work, while an average employee cost $528 dollars (30). Indicating that missing work from IBS symptoms significantly impacted productivity of the company. IBS can be a significant financial burden for not only the patients, but also the employers of the
Irritable Bowel Syndrome with Constipation

patients (30). When total medical costs were calculated for a group of 7,652 patients in 2010, it was found that IBS-C patients spend $1,335 more than control patients for medical costs (31).

**Regional Care Differences**

Healthcare utilization also differs across the US for IBS-C patients. A study in Olmsted County, MN in 2008 found that costs for IBS-C patients were higher than controls (32). Additionally there were higher imaging and procedure costs (32). Interestingly, IBS-C patients experienced differing procedures and imaging depending on their primary hospital or provider (32). Healthcare resource use for IBS-C greatly varies across the US. Insurance claims were evaluated for 35,627 IBS-C patients (33). 77.2%

![Figure 10. Most frequent tests in different regions in the United States. Lacy et al. PLoS 2016.](image)

were male and mean age was around 50 years old (33). Patients needed two diagnoses for
IBS-C, 12 months of continuous healthcare for IBS, and to be older than 18 years old to be included in this study (33). Colonoscopy was the most frequently conducted test, however, only 44.9% of IBS-C patients had a colonoscopy (33). CT scan greatly varied in prevalence and was most common on the East coast (33). Anorectal function testing only occurred in a few states (33). This is likely because of lack of equipment in many facilities (33). Only 2.7% of IBS-C patients had this testing done (33). Finally, ultrasound was more common in the Mid-West to Eastern states, and 35.2% of IBS-C patients had an ultrasound conducted (33).

Additionally, patients were likely to have multiple tests (33). Over a third, 36.3%, of patients had three or more tests within a two-year period (33). Pharmacy prescriptions for treating IBS-C were also higher in IBS-C patients (33). About a third of patients had a prescription for their IBS-C symptoms (33). This varied regionally as well though. Hawaii, Louisiana, Kentucky, and Virginia were most likely to have a prescription for their symptoms (33).

![Pharmacy Prescriptions for Treating Constipation or Diarrhea](image)

*Figure 11. Frequency of pharmacy prescriptions for treatment of IBS-C in the United States. Lacy et al. PLoS 2016.*
Conclusion

IBS-C is a complicated and difficult disease. The patient experiences discomfort, quality of life detriments, and the toll of IBS-C is large. Treatment is not the same for every patient, and many patients will require multiple modalities to experience relief. Serotonin is a great source of treatment for IS-C because of its implications in gut homeostasis. IBS-C patients have decreased serotonin secretion, and focusing on this aspect in care is important. The research has just begun to scratch the surface of IBS-C; however, more personalization and medicinal advances are on the horizon.

Many of these studies had a very small group of subjects and were from small geographic areas. The studies are not necessarily representative of the whole population of IBS-C patients. Additionally, many previous studies grouped all types of IBS together. Recently researchers have seen the error in that classification, however, newer type specific research is just beginning. All of these reasons mean results are not necessarily representative to true etiology and presentation. However, they are a good starting point.

The implications of these studies are small when individual merit is considered. However, when combined from a clinical standpoint, together they provide an easy reference for clinicians to decide treatment for their patients, as there is no current standard treatment. Additionally, it could motivate physicians to seek combined treatment to more quickly improve patients’ quality of life. Many patients take years before they feel improvement costing themselves, medical facilities, and the economy significant money. Focusing on patient relief can help physicians improve their patients’ quality of life faster. One patient having an improved quality of life because of a study is of great
benefit considering the long-term side effects and quality of life detriments caused by IBS-C.

**Future Work**

These regional differences are especially interesting because the Midwest is not often a center of studies. Diet differs across the country, and treatment of a gastrointestinal syndrome could likely differ with that as well. Understanding the different effective treatments for specific regions could vastly improve patient care and health outcomes. Thus, we are interested in understanding care for IBS-C in North Eastern South Dakota.

We created a survey with the intention to distribute it at Avera Medical Care Group in Brookings, SD. Unfortunately, due to extenuating circumstances the survey could not be distributed within this timeline. We plan to extend the survey to medical centers across South Dakota including rural and metropolitan areas. We hope to analyze perceptions, treatment types, and treatment efficacy across the state.
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