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Case Report

Treating Irritable Bowel Syndrome (IBS) with A Dopamine Agonist Can Effectively Ameliorate this Condition Despite being Refractory to Standard Therapy

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Abstract

A name has been coined to describe a large variety of chronic medical disorders involving multiple different organ systems that have in common the quick efficacious response to dopamine agonist therapy. Described for the first time are case reports with long-term severe symptoms of Irritable Bowel Syndrome (IBS) that had a great quick positive beneficial response to treatment with the dopamine agonist dextroamphetamine sulphate. The hypothetical mechanism as to why dopamine agonists are so effective is to diminish excessive cellular permeability which allowing infusion of unwanted toxic elements into tissues or organs that cause inflammation and mitochondrial dysfunction. This can lead to subsequent muscle motility disorders by hypothetical mitochondrial dysfunction by these unwanted elements adversely permeating mitochondria. What makes these cases even more interesting is that the same treatment was effective for two different types of IBS, i.e., Diarrhoea (IBS-D) and Constipation (IBS-C) which seems to be polar opposites. Even more interesting is that IBS-D responded so well to a dopamine agonist when one of the standard treatments for IBS-D are dopamine receptor antagonists.

Keywords: Irritable Bowel Syndrome, Diarrheal, Constipation, Abdominal Pain, Dopamine Agonist, Increased Cellular Permeability Syndrome

Introduction

Irritable bowel syndrome is a common chronic functional bowel disorder characterized by abdominal pain associated with defecation or changes in stool form or consistency and frequency. It has a prevalence worldwide of about 5% (ranging from 4 to 10%) [1-3]. The Rome IV criteria divide IBS into four different entities based on clinical manifestations: 1) IBS with constipation (IBS-C), 2) IBS with diarrheal (IBS- D), 3) IBS with a mixed pattern of constipation and diarrheal (IBS-M), and unclassified IBS [4]. Division into these 4 categories is aided by using the Bristol Stool Form (BSF) which characterized 7 different types of stools seen with the bowel movements. With IBS-D at least 25% of bowel movements present with BSF 6 (fluffy mushy type stool) or 7 (watery with no solid components) and less than 25% BSF 1 (separated hard lumps) or

BSF 2 (hard and lumpy resembling a sausage). For IBS-C one should have 25% of the stools categorized as BSF 1 or 2 less than 25% are BSF 6 or 7. With BSF-M more than 25% of the stools can be classified as BSF1 or 2 and more than 25% are BSF 6 or 7. The stool should be evaluated when there is the presence of abdominal pain [5].

The actual mechanism responsible for the symptoms of IBS is not known with certainty [6]. It is well known that emotional stress can be associated with change in bowel movements, causing abdominal pain and diarrheal. Simply changing environments can lead to constipation and abdominal pain. Mucosal barrier function, intestinal, motility, and mucosal secretion can be influenced by connections between the central nervous system and the myenteric plexus [7]. A priori, it seems logical that there may be different physiological factors responsible for IBS-D versus IBS-C. For example, one factor that is thought to be more responsible for IBS-D versus IBS-C is increased intestinal permeability and sensitivity to visceral and somatic stimuli [8,9]. IBS-D and IBS-C may be influenced by differences in the 5-hydroxytryptamine (HT) pathway which influences bowel motility. There is, in fact, evidence that dysmotility with hyperactivity is at least partially related to excessive 5-HT as evidenced by higher plasma level levels of 5-HT [6,10]. The plasma level levels of.5-HT are decreased with IBS-C [6].

Indeed, antagonists of serotonin 5-HT3 receptors, e.g., alosetron, ondansetron, and ramosetron, originally developed to inhibit the nausea from chemotherapy for cancer, have shown efficacy for treating IBS-D and improving symptomatology (especially alosetron [11]. They seem to slow colonic transit time [11]. However, they are not considered top choices for therapy since in higher dosages, there was observed an increase in ischemic colitis [6]. Indeed serotonin (5-HT) which contributes to smooth muscle relaxation and contraction and visceral perception may play a significant role in the pathophysiology of IBS-C. There are data suggesting that IBS-C may be related to a decreased cellular release of 5-HT in the gastrointestinal tract [12]. Thus drugs e.g., tegaserod which is a 5-HT4 receptor agonist has been found to provide clinical benefits for IBS-C. Related to cardiovascular adverse events in higher dosages tegaserod at 6mg twice daily is approved for treating IBS-C in women younger than age 65 without cardiovascular decrease [13].

Selective serotonin reuptake inhibitors e.g., sertraline and paroxetine, have been used to improve abdominal pain associated with IBS. Since constipation and infrequent bowel movements versus diarrheal and frequent bowel movements are opposites, it is logical to think that the treatments for each type would be different. Indeed, for IBS-D, treatment may involve peripheral opioid agonists e.g., loperamide, or bile acid sequestrants e.g., cholestyramine or colestipol, or 5-HT3 receptor agonists (as previously mentioned or mixed opioid antagonists/ agonists e.g., eluxadoline or non-absorbable antibiotics e.g., rifaximin [11,14]. For IBS-C suggested treatments include soluble fibbers, laxatives, type two chloride-channel activators e.g., lubipristone and guanylate-c agonists e.g., linaclotide [11,14]. For abdominal pain, in both types, anti-spasmodics, tricyclic antidepressants, and selective serotonin reuptake inhibitors have been used with varying degrees of success. There is definite overlap in symptoms and signs in IBS-D and Crohn's disease, ulcerative colitis, and microscopic colitis, and sometimes the demarcation is not clear. Similarly, there may be similar symptoms and signs in patients with IBS-C and gastroparesis and pseudo intestinal obstruction or very severe constipation with very long intervals between bowel movements.

Interestingly, there is a different class of drugs, i.e., dopamine agonists, that have proven very effective for more severe problems of very frequent bowel movement, diarrheal, and abdominal pain, i.e., ulcerative colitis, Crohn's disease, and microcytic colitis, despite being refractory to standard therapy [15-19]. What is very interesting is that severe gastrointestinal disturbances refractory to standard therapy associated with abdominal pain, and infrequent bowel movements and constipation e.g., gastroparesis, pseudointestinal obstruction and pathological constipation (bowel movements once in nine days to eight weeks) have also quickly, and quite effectively, responded to treatment with dopamine agonists [20-24]. One of the functions of dopamine is to diminish cellular permeability. There is a hypothesis that a large variety of chronic illnesses are related to increased cellular permeability leading to the abrogation of the mucosal barrier. This allows the infiltration of irritants and noxious elements that results in inflammation and/ or mitochondria dysfunction which can lead to disorders of skeletal or smooth muscle activity [25,26]. This hypothesis was an off-shoot of studies trying to determine whether the development of spiral arteries to allow nutrient exchange between mother and fetus may require autoimmune stripping off of the thick cellular walls of the uterine arteries in the proliferative phase to create arteries with a cell wall that is only one cell thick, (i.e., spiral arteries) but then to determine how the pregnant woman avoids immune rejection of the fetus because of the increase in cellular immunity [27-30].

Dextroamphetamine sulphate stimulates the release of more dopamine from sympathetic nerve fibbers. It is a dopamine agonist, but another term in that it is a sympathomimetic amine. This has been the main dopamine agonist that we have used to successfully treat a wide variety of chronic conditions in both females and males. This helps to support the increased cellular permeability hypothesis as the initial event in a large number of chronic illnesses, both gastrointestinal and non-gastrointestinal [31-33]. The aforementioned cases of gastrointestinal disorders, both inflammatory bowel disease and hypo-motility disorders, were all treated with dextroamphetamine sulphate [15-24]. Sometimes inflammatory bowel disease co-exists with other manifestations of the increased cellular, permeability syndrome and dextroamphetamine sulphate ameliorates not just the gastrointestinal problem but all of the other conditions [33]. There is evidence that dextroamphetamine not only aids in ameliorating the gastrointestinal disturbances, but helps correct infertility and tendency for miscarriage even in women with diminished

oocyte reserve. The oocyte depleted state was probably related to increased cellular permeability with the resulting inflammation leading to autoimmune oocyte damage [16,18,24].

As of this date, we have not published any case reports of the use of dopamine agonists for treating IBS-D or IBS-C, nor could we find any reports in the literature outside of our group. Presented here are two case reports including one woman with IBS-D and one with IBS-C. Both responded quite well to the dopamine agonist (and sympathomimetic amine) dextroamphetamine sulphate.

Case 1– IBS-D

A 10-year-old girl was diagnosed as having IBS-D. This was based on her symptoms of very painful, totally watery, bowel movements most often twice per day. Even when she had only one bowel movement, it was still associated with pain and was watery. She stated that even when she took loperamide, which helped her stool to be mushy rather than watery, it was still painful. She would frequently have nausea and vomiting, especially if she ate certain trigger foods e.g., onions and green pepper. She was given acidophilus and probiotics that did not help. She stated that up until the year 2015 she never had one day that she could remember with no pain and a formed stool. A colonoscopy which she had as an adult failed to show evidence of inflammatory bowel disease. In addition to her gastrointestinal symptoms, the patient also had severe dysmenorrhea, heavy menses, chronic fatigue, and headaches. At the age of 29, she consulted our group predominantly for the dysmenorrhea and heavy menses. The oral contraceptives that she had been prescribed by other physicians resulted in significant reduction in the heavy bleeding. However, it did not help with the dysmenorrhea. It also worsened her headaches. She was not anemic to explain the fatigue.

We discussed with her that most likely she was suffering from the increased cellular permeability syndrome which could explain all of these clinical entities [25-30]. We advised her that of the various dopamine agonists, the one that we have had the most experience with is dextroamphetamine sulphate. Eventually, the dosage that ameliorated her IBS-D, dysmenorrhea and fatigue was 25 mg of extended-release amphetamine salt in the a.m. and 30 mg immediate release tablet at noon. She stated that there was at least a 95% improvement in all of her symptoms. Her stools were now completely formed and not associated with any pain. Interestingly, initially her prescription plan only would pay for brand-name drugs. However, her insurance changed and now the new prescription plan would only pay for generic medications. Related to a much higher cost, she switched to 30 mg immediate release generic tablets of amphetamine salt in the a.m. and 30 mg IR tablet at noon (30 mg of amphetamine salts provides 18.8 mg of the active ingredient dextroamphetamine sulphate). She did not find the generic nearly as effective. We advised switching to another generic but related to shortages, the pharmacist could not obtain a different manufacturer.

The patient decided to pay out-of-pocket for the brand name. Her symptoms immediately abated once again so that she was at least 95% improved. This improvement had persisted for11 years. However, in the last two years, to save money, she frequently would take only the 25mg extended-release amphetamine salt capsule or the 30 mg IR tablet. With the reduced dosages she states that the IBS-D is still reasonably controlled without any pain, but with one mushy bowel movement about once per day. Her fatigue is still markedly improved. The reduction though, has caused an increase in previous severe dysmenorrhea, which had been 95% abated. However, now she was having only one day of moderate dysmenorrhea per month [34].

Case 2- IBS-C

This female patient consulted us at age 39 for recurrent miscarriages X5. Some of her miscarriages were natural and some were following in vitro fertilization. In at least 3 of miscarriages she took progesterone supplementation starting post ovulation and until the time of miscarriage. We suggested treatment with a dopamine agonist to inhibit the possibility of increased cellular permeability syndrome, allowing a more robust cellular immune reaction for the autoimmune remodelling of thick-walled uterine arteries to create thin-walled spiral arteries that are not being negated sufficiently by the increase in immunomodulatory proteins that are the result of activating membrane progesterone receptors [35-37]. The suspicion of possible excessive cellular immune activity causing immune rejection of the fetal semi allograft was heightened by the knowledge of diminished ovarian reserve (as evidenced by low serum anti-Mullerian hormone levels) in absence of a known surgical or anti-cancer drug treatment [38].

She also mentioned that she has been suffering with severe IBS-C for 20 years Although her bowel movements were not that infrequent occurring every 3 to 5 days, they were “hard and pellet like.” Moar importantly, however, was that it could take an hour for the stool to pass. During that time the mid epigastric pain would be so severe that she would be doubled up with pain. She would have hours of mid epigastric pain during the 3 to 5 hours before the bowel movement, which intensified and increased in frequency as she got closer to the time when she could eventually defecate. However, the pain was not nearly as excruciating as the time when she was in the process of defecating. We explained to her that not only may the dextroamphetamine help her to conceive successfully, but from our experience, it has a good chance of improving the IBS-C [24]. It should be noted that 5 years earlier the bowel movements were associated with haematochezia and thus a colonoscopy was performed. The colonoscopy did not show any inflammatory changes and was thus consistent with IBS and a biopsy showed no evidence of microscopic colitis. The source of bleeding was found to be internal haemorrhoids.

We generally initiate treatment at 15 mg amphetamine salt upon a rising and at noon and we will increase the dosage by 5

mg if there were lack of side effects but insufficient correction of symptoms that could be related to increased cellular permeability. After just one month of treatment, with a total dosage of 18.8mg dextroamphetamine sulphate, the patient reported the absence of tenesmus with bowel movements every other day that were softer and of normal consistency with painless easy passage without straining. It should be noted that she had tried stool softeners and various types of fibber preparations in the past that did not help her IBS-C. Linaclotide, which she had been prescribed at age 30, did not improve symptoms so she stopped taking this drug.

Discussion

Case reports are in modern times given more credence than in the past when the emphasis was knowledge propagated by properly performed randomized controlled studies. A non-conventional treatment of a condition that shows efficacy in a very convincing case report allows a physician faced with a malady causing a detriment to quality of life could influence that physician to offer an "off label" therapy instead of merely sympathizing with the patient or subjecting the patient to a progression of referrals to different specialists to hopefully find one with the answer to the problem. We have coined the term, the increased cellular permeability syndrome for a plethora of seemingly unrelated conditions involving multiple different organ systems that all have in common response to treatment with dopamine agonists. We chose dopamine agonists based on the hypothesis that a high percentage of medical conditions may have as the initial pathological event the failure to preclude irritating or physiological disrupting agents abrogating a mucosal barrier and infiltrating a given tissue or organ. The great response to dopamine agonist therapy in so many conditions that were refractory to standard or conventional therapy helped to support this hypothesis.

However, it does not prove for sure that the beneficial action is, in fact, by decreasing abnormal increased cellular permeability. We chose to present these two cases of IBS for several reasons. Dopamine receptor antagonists are considered one of the "standard" ways of treating IBS-D, possibly these dopamine antagonists may be useful once the cascade of events that follows the initiating event (i.e., abrogation of the mucosal barrier by inflammatory elements). However, the benefit of dopamine agonists, providing marked relief of IBS-D when dopamine receptor antagonists have failed, lends credence to this hypothesis of increased cellular permeability as the cause of IBS-D. Furthermore, since standard therapy for IBS-D and IBS-C are different and do not overlap, the demonstration that a dopamine agonist provided marked relief of both conditions supports the concept that most chronic disorders have as their initial basis increased cellular permeability.

One of our goals is not only to spread the word to help people around the world also suffering from various conditions that are refractory to conventional therapy, who probably would respond to dopamine agonists, but also to generate interest in subspecialists or pharmaceutical companies to create even more effective dopamine agonists, possibly with even less side effects. Alternatively, another objective is to determine a treatment paradigm that can mix conventional therapy to dopamine agonist therapy to provide even more efficacious treatments. Though we have treated many cases of IBS over the years with good success with dopamine agonists, we have never previously published about IBS. We purposely chose these two cases, not only because they represent opposite ends of the IBS spectrum with diarrheal vs constipation, but because of how many years they had suffered and how quickly they responded to dextroamphetamine. One criticism of case reports is the question of how can you be sure that the positive outcome was not a fortuitous remission? These two cases suggest the possibility of spontaneous remission to be highly unlikely. Nevertheless, spontaneous remission is still possible or "the power of suggestion" prevailed. There is indeed a psychogenic component to IBS [39]. Recently we decided to target different subspecialties to present interesting cases that had long-term suffering but responded well to dopamine agonists. A most recent group that we targeted were dermatologists. Thus, we published case reports recently on successfully treating a variety of skin disorders including generalized pruritus without skin lesions [40], cutaneous discord lupus [41], bullous pemphigoid [42], palmoplantar eczema [43,44], dystrophic epidermolysis bullosa [45], erythromelalgia [46], and pyoderma gangrenosum [47].

Thus, we have now turned our attention to the gastrointestinal subspecialty either writing about types of cases never before reported or new cases that provide more insight about the barriers that exist to provide treatment. Furthermore, our objective is to provide more insight into the relative efficacy of different dopamine agonists. Also, we want to make physicians aware that pathological conditions of the alimentary tract may co-exist with co-morbidities in other organs Thus, one may choose dopamine agonists over standard therapy even if standard therapy is improving the gastrointestinal condition to allow amelioration of other maladies. Gastrointestinal disorders have been associated with other conditions also related to increased cellular permeability. We published a case report of a woman who suffered from severe chronic pelvic pain, mittelschmerz, and dysmenorrhea who also had treatment refractory Crohn's disease. Her suffering in all categories was markedly ameliorated with dextroamphetamine treatment [33]. But suppose that she had responded to tumour necrosis alpha inhibitors for her Crohn's disease, e.g., adalimumab. The adalimumab would have only corrected Crohn's disease but not pelvic pain.

Indeed, case one had severe dysmenorrhea, headaches, and chronic fatigue plus IBS-D. All of these symptoms, not just the bowel issues, responded to dextroamphetamine sulphate. The increased cellular permeability syndrome may be associated with diminished oocyte reserve plus bowel pathology even in the absence of pelvic pain or the presence of endometriosis. The use of dopaminergic drugs rather than other treatments for disorders associated with abdominal pain and diarrhoea can inhibit immune rejection of

the foetus thus inhibiting miscarriage and correcting infertility as seen in any recent cases of improving infertility, ulcerative colitis, and Crohn's disease [16,18,24,48]. The treatment with dextroamphetamine sulphate not only markedly ameliorated eating induced mid-epigastric pain of unknown ethology, but allowed a teenager to improve her egg reserve [49]. The dextroamphetamine sulphate not only improved gastrocolic reflux in a young man but inhibited recurrent aphthous stomatitis [50].

Dopamine agonist e.g., dextroamphetamine have not only improved severe abdominal pain but have provided a high quality of life in patients with abdominal pain who were told that they only had a few months to live e.g., a woman with autoimmune hepatitis and a male with very severe post-prandial pain related to mesenteric sclerosis [50,51]. One of the cases of extreme severe abdominal pain in an extremely cathectic male who was told death would probably occur within 3 months, was a man with severe chronic pancreatitis whose pain was not ameliorated by a combination of oxycodone, OxyContin, and fentanyl [52]. At the 8-month mark following treatment with 90mg amphetamine salts he was pain-free. At the 6-month mark he was completely off all of his opiates and gained 50 pounds back [52]. For convenience we suggested that he could consider switching his care to his pain management doctor who prescribed the high dosage opiates, because the patient was geographically a lot closer to this physician. The pain management physician actually refused to write for amphetamines because he thought he may get into trouble!

Another case was reported where a woman suffering for several years with another alimentary disorder, achalasia, that was refractory to other therapies responded very well to dextroamphetamine [53]. Interestingly, her father, an internal medicine specialist, and her brother, a gastrointestinal specialist, convinced her to stop the drug even though she has no side effects and her symptoms had markedly improved. When her symptoms returned after stopping the dextroamphetamine they admitted her to a mental hospital to evaluate her for a psychosomatic illness. When no psychosomatic illness was found to treat, she resumed the dopamine agonist and her symptoms once again abated [53]. Despite 50 years of prescribing the dopamine agonist dextroamphetamine to hundreds of patients, no one has ever been addicted to the drug. The drug can be stopped suddenly without withdrawal symptoms. Ir has never been associated with an adverse event that required hospitalization or death, and it is safe to use during pregnancy. Yet there seems to be a tremendous bias against this drug for unknown reasons. This drug is used for children with attention deficit hyperactivity disorder and yet has the same narcotic restrictions as fentanyl. Thus, these restrictions make this drug difficult to obtain.

Therefore, it may be needed to evaluate other dopamine agonists to evaluate their efficacy in some of the same type conditions successfully treated by dextroamphetamine. Indeed, the dopamine agonist cabergoline has been reported to provide relief for 4 non-gastrointestinal symptoms that affected the quality of life, e.g., dysmenorrhea, headaches, chronic fatigue, and carpel tunnel syndrome [54-56]. However, based on another case report, it seems that amphetamines and carbidopa levodopa are more effective treatments than cabergoline since both amphetamine salts and carbidopa levodopa completely abrogated severe long-term migraine headaches, chronic regional pain syndrome of the leg, and constant eyelid twitching in a woman whereas cabergoline only ameliorated the severe treatment refractory headaches [57]. For a gastroenterologist deciding on treating a particular illness one has to consider efficacy, risks, side effects, and costs. We already mentioned cases of IBD that were refractory to Tumour Necrosis Alpha (TNF alpha) inhibitors yet responded quite well to dopamine agonists. However, even if both drugs were equally effective one has to consider the long-term potential side effects of TNF alpha inhibitors e.g., development of cancer and serious infections, and though uncommon, some adverse events that can lead to sudden death. These risks are not found with dopamine agonists.

Furthermore, the cost of these TNF alpha drugs may be $500,000 per year whereas generic dopamine agonists may be only 0.2% of the cost. Unfortunately, it costs $3 billion dollars to get a new drug to market so reimbursement once approved is very costly. This drives the cost of healthcare skyrocketing so that many countries are facing a healthcare crisis. Many times, the quest to develop new drug therapies is because standard conventional therapies are not that effective. If the medical profession would be more open-minded about the use of dopamine agonists, not only for gastrointestinal issues, but for many chronic illnesses, the cost of healthcare could potentially drop significantly, thus providing a medical service for a

large number of people who cannot afford very expensive healthcare. One could try generic dopamine agonists first, and only if not effective, try treating with these other medications. Possibly some conditions may not respond as well to dopamine agonists but respond better to other drugs on the market. Possibly this case report will generate interest in a pharmaceutical company to develop a better dopamine agonist than what is presently available to treat various conditions that may be related to increased cellular permeability.

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Conflict of Interest

None.

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