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Long-term amelioration of severe mixed irritable bowel syndrome (IBS-M) and other clinical manifestations with treatment with the dopamine agonist dextroamphetamine sulfate

Abstract

There are many patients with abdominal pain with or without bowel motility disorders that were refractory to standard therapy, but responded to dopamine agonists, e.g., dextroamphetamine. These conditions can be associated with hypermotility bowel issues with diarrhea e.g., ulcerative colitis, Crohn's disease, and microscopic colitis, or hypomotility disorders e.g., gastroparesis pseudo intestinal obstruction, and severe constipation. The hypothetical mechanism for all of these pathological conditions is that they are all initiated by increased permeability of that tissue, allowing infusion of unwanted elements that either caused inflammation or muscle dysfunction. The theoretical mechanism of how the dopamine agonists benefit so many disorders is that dopamine functions to decrease cellular permeability. Interestingly, once the condition is initiated certain symptoms e.g., diarrhea, can be helped by treating with dopamine receptor antagonists. Though we have treated successfully many cases of Irritable Bowel Syndrome (IBS) with dopamine agonists, until recently we've not reported any of these cases. One purpose of the two new case reports was to show that once IBS is initiated the treatment for the type with diarrhea (IBS-D) is completely different than the one with constipation (IBS-C), yet one treatment, i.e., dopamine agonists can provide the treatment with the best success. We present for the first time a case of mixed IBS (IBS-M) with constipation at times, and twice as frequently with diarrhea, showing that one drug can effectively treat both phases in one person. We emphasize in the case with IBS-D she had long-term improvement (IBS-D perfectly controlled for 50 years starting at age 16). We use these cases to show that the increased cellular permeability syndrome may also be associated with other conditions, e.g., headaches or dysmenorrhea which also improved with dopamine agonist therapy.

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Introduction

Many conditions seem to have a higher chance of other maladies associated with them. For example, pelvic pain and endometriosis can be associated with clinical pathology in unrelated areas of the body as recently published in a case report [1]. Even Parkinson's disease may be associated with an increased risk of stomatodynia and vulvovaginitis [2]. Ford et al. found that treatment of Parkinson's disease with levodopa carbidopa not only helped the neurological issues but eradicated the vulvovaginitis [2].

This is consistent with the studies we have performed trying to evaluate the mechanism of how the fetal semi allograft escapes immune surveillance to see if cancer would "borrow" the same mechanisms. There does appear to be a method of avoiding immune surveillance that has led to novel highly effective treatment for very advanced cancers of all types that were no longer responsive to standard or clinical trial anti-cancer therapies [3-9].

One of the important steps for successful implantation is to develop arteries with a very thin cell wall (1 cell thick) to allow nutrient exchange between mother and fetus. Neovascularization would require a genomic process, acting through the nucleus, which is generally a slow process. The time of appearance of these thin-walled arteries, known as spiral arteries, appear shortly after the increased secretion of progesterone (P) by the corpus luteum. Thus, it seemed more logical that the formation of spiral arteries may be accomplished by remodeling of the thick-walled uterine arteries found in the proliferative phase by an autoimmune process [10]. One hypothesis was that the newly made P could inhibit a chemical in the body that probably functions to diminish cellular permeability. Evidence suggests that this chemical is dopamine. Subsequently the infiltration of unwanted "irritants" abrogates the mucosal barrier could induce a cellular immune reaction, which could play a vital role in the autoimmune stripping off of the thick cell walls of some of the uterine arteries, and then replacing them by single cells shed from the extra villous trophoblast on day six subsequent to fertilization [10].

The next question to consider does somehow the fetal-placental unit exclude the increase in cellular immune cells from the fetal microenvironment or not? Studies found that the cellular immune cells do invade the fetal-placental microenvironment, and 70% of the cells are Natural Killer (NK) cells, 20% macrophages and 10% cytotoxic T cells [10]. However, these cellular immune cells next somehow have their killing activity neutralized by the time the blastocyst implants. Research studies by our group and others support the hypothesis that the suppression of the destroying activity of the cellular immune cells is accomplished by P activating fast action Membrane Progesterone Receptors (MPRS) [8,11,12].

In the pelvic tissues, according to this model, the normal degree of stimulation of these inflammatory cells is not associated with any adverse symptoms. However, excessive cellular permeability may lead to excessive infiltration of irritants into pelvic tissues, causing various pelvic symptoms. Could this explain why almost all women with Parkinson's disease, (which is a disease of dopamine deficiency) who had vulvodynia responded to the levodopa carbidopa given to treat Parkinson's disease [2]? Indeed, there is good evidence that the treatment with dopamine agonists could ameliorate not only vulvodynia, but also many other types of pelvic pain [13-20].

The increased cellular permeability that occurs following ovulation, could explain why some of these pelvic pathological conditions may exist only during the luteal phase, especially closer to the time of menses. Thus, it is possible that relative dopamine deficiency can lead to both pelvic and non-pelvic morbidities that only occur in the late luteal phase [21]. However, excessive cellular permeability may exist in the pelvic tissues or the tissues of various extra pelvic sites, and are present, not just in females, but males also (what they all have in common is that they all respond to dopaminergic agonists even when conventional therapy has failed) [22-25].

We have been treating these various disorders for over 50 years. The decision was made to use the dopamine agonist dextroamphetamine sulfate rather than carbidopa-levodopa because this drug used for Parkinson's disease had a high rate of nausea and vomiting (at least for the first couple weeks) and had the risk of extrapyramidal side effects (at least in high dosages).

We can state that having treated hundreds of patients over 50 years with treatment refractory conditions involving practically every organ system, that almost everyone showed significant improvement of their pathological condition following dopamine agonist treatment. Fifty years ago, case reports were not as popular as they are becoming today. Thus, we had treated many patients successfully without reporting them. Finally, the first case report we wrote concerned long-term, very severe urticaria being influenced by one of the co-authors who referred the two cases to this author. This first published case report occurred about 10 years after treating so many of these cases [26]. However, despite evaluating and helping a lot of cases for this ubiquitous syndrome involving increased cellular permeability, we were not involved in writing another case report until six years later influenced by an internal medicine resident who referred the case, but was interested in publishing the case report to help him get into a gastrointestinal residency. Thus, we reported a treatment refractory case of achalasia that responded very well to the dopamine agonist dextroamphetamine sulfate [27].

Before proceeding with another extremely interesting case report, a few things need to be mentioned. First, because dextroamphetamine stimulates not only releases dopamine, but also catecholamines, though based on our research, we chose dextroamphetamine because for its dopaminergic effect, one could still not state with certainty that the beneficial action was not from the increased release of epinephrine or norepinephrine. Furthermore, we chose dextroamphetamine sulfate because at least another clinician and researcher, David Streeton, used dextroamphetamine sulfate to successfully treat a condition called idiopathic orthostatic edema [28].

One of the few randomized studies we performed evaluated the efficacy of dextroamphetamine sulfate in patients with idiopathic edema. However, we included a much milder form than described by Streeton et al. We evaluated women who were gaining weight that could not be explained by nutritional intake [29]. Thus, initially without the right term to call this condition, and because many of the patients (especially women) had difficulty losing weight, we described other clinical manifestations as part of the condition called idiopathic orthostatic edema [25]. So many patients that we were treating had some type of pain syndrome, so we started using the term sympathetic hyperalgesia-edema syndrome [30]. However, it was clear that dopamine agonists could help with certain

conditions not associated with edema, unexplained weight gain, or pain, e.g., chronic fatigue syndrome. So, we coined the term the increased cellular permeability syndrome [31]. Chronic fatigue syndrome is one of the few conditions under the umbrella of increased cellular permeability syndrome in which we published a larger series. We showed that 48 out of 50 reported a marked improvement and two moderate improvement following treatment with dextroamphetamine sulfate [32]. Since some of these patients did not have inflammatory disorders or unexplained weight gain or edema, yet still responded to dopamine agonists, this was the basis for coining the term increased cellular permeability syndrome. This is our term and it has not been officially designated as a medical disorder.

This condition, despite a plethora of case reports, but without the backing of pharmaceutical companies, is not known by the majority of practicing physicians. The lead author of the case study published here is now 80 years old and thus feels an intensified need to share this information with other physicians since so that many people can be relieved of their suffering. Therefore, lately, the number of case reports have been increased despite hundreds of cases seen in the last 55 years. Generally, we have only published case reports of a new clinical manifestation of the increased cellular permeability syndrome that has had a great response to dopamine agonists, or if a different dopamine agonist was used to improve the syndrome rather than dextroamphetamine sulfate, or a different combination of multiple symptoms.

We chose this case that is reported here for several reasons. For one, though recently, for the first time, we described two cases of Irritable Bowel Syndrome (IBS), one with diarrhea, and the other with constipation, we have never published a case report as yet on mixed IBS (IBS-M) where the same person is plagued sometimes with diarrhea and sometimes constipation. Second, this case demonstrates not only improvement in abdominal pain and diarrhea and constipation, but improvement of other manifestations of the increased cellular permeability syndrome e.g., idiopathic edema and weight gain, but also headaches, which is a common manifestation of this syndrome [33-36]. Dopamine agonists also markedly improve severe dysmenorrhea [19].

Third, the case is presented to show that this type of therapy does not lose its beneficial action over time. She is one of the earlier cases that we treated eight years before our first publication of urticaria i.e., she has had 50 years of treatment.

Case report

A 16-year-old female consulted us for several conditions, but predominantly because the lead author was both a medical and reproductive endocrinologist. Her main symptoms were rapid weight gain despite severe dieting stating that her typical meal for the whole day would be 4 shrimp and 2 eggs. Her parents thought there may be some endocrine cause of this weight issue that was unexplained. Several pediatricians were unable to find a cause. Serum thyroid test and cortisol levels were normal and the pediatricians suggested a consult by an endocrinologist. Because she also suffered from severe dysmenorrhea, the parents thought the best physician to evaluate their daughter, was one trained in both medical and reproductive endocrinology.

Following further probing her full history, it was found that she was suffering with severe IBS-M that started around puberty at age 12. When she had the IBS-D part of the IBS-M present, she would get mid-epigastric pain episodes that were only relieved by defecation of watery stools. These episodes of diarrhea would be a minimum of three per day but sometimes up to eight times per day. Though the diarrhea phase would be more frequent (70% of the time), she dreaded the constipation phase even more because the mid-epigastric pain was more severe. The only relief to the pain was to defecate a hard rock-like stool. However, it could take an hour to pass the stool which required marked straining, and she typically would have severe diaphoresis while defecating. She stated that for years there never was a time span where her IBS-M seemed to be in remission. She also suffered from severe headaches at least twice per week.

Following treatment with dextroamphetamine sulfate extended-release capsules 15 mg two times per day, she lost all the extra weight back to a weight appropriate for her height, she no longer had headaches, and no longer suffered from dysmenorrhea. Furthermore, her IBS-M completely resolved and she would have one daily painless bowel movement.

Patients with this condition of increased cellular, permeability syndrome frequently have problems conceiving which is sometimes compounded by Diminished Ovarian Reserve (DOR) [37,38]. In her case, we helped her to conceive naturally without the use of assisted reproductive technology combining dopamine agonists and progesterone supplementation in the luteal phase [39,40]. She had two children under our care. The safety of using dextroamphetamine during pregnancy was not as well-known 35 to 40 years ago, so she stopped the dopamine agonist once she became pregnant. With known safety of the drug during pregnancy, today, when someone new has severe manifestations of this disorder, whether gastrointestinal or not, we advise continuing the drug to term [41-43].

Before her pregnancies, and pre-dopamine agonist therapy, the IBS-C phase of her IBS-M only occurred 30% of the time. Interestingly, when she stopped the dextroamphetamine sulfate during both pregnancies, her IBS-M returned but was 100% of the time with constipation. The IBS-M which possibly during pregnancy state could be called IBS-C, completely resolved when she started once again the dextroamphetamine sulfate. She elected not to nurse the baby so she could restart dextroamphetamine sulfate sooner. Today we allow the drug to be given even while nursing because no adverse events have been noticed in the babies. She did not take any prenatal vitamins with iron during the pregnancy.

The woman is now 66 years of age and has been treated with the dopamine agonist for 50 years. She makes note of the fact that she has had such perfect health that this is the only medication that she takes. She has not developed any other medical conditions in the 50 years of taking dextroamphetamine sulfate.

Discussion

We have treated many cases of IBS over the years quite successfully with dopamine agonists especially dextroamphetamine sulfate. Yet, only until recently we presented two cases of severe IBS, one with IBS-D and one with IBS-C [44]. The case of IBS-D of this aforementioned case report was similar to this case in that she has been successfully treated without side effects for many years [44].

One of the goals of presenting another unique case that has never been published before i.e., (treating IBS-M) is to promote the concept of the increased cellular permeability syndrome and how effective are dopamine agonists in ameliorating so many chronic disorders. Despite that it is now over 40 years since our first publication, and despite over 100 publications demonstrating the marked efficacy of these drugs (especially dextroamphetamine sulfate), and despite an absence of articles disputing the clinical benefits of dopamine agonists, there seems to be an intense effort of governmental agencies to make it difficult to obtain dextroamphetamine. There has been in the state of New Jersey, which is where our medical school and hospital is located, a law that precluded the writing of any drug with a class II narcotic restriction from being prescribed off-label. One may ask why is this drug that is used for children with attention deficit hyperactivity disorder, being placed in the same narcotic category as fentanyl?! Nevertheless, for over 30 years, that problem was obviated by only treating those who did not also have attention deficit disorder to receive their first prescription and the quarterly visits for prescription of dextroamphetamine sulfate by treating them in our other medical office which is located in Pennsylvania, a state which does not have that strange law.

However, in 2021, the Attorney General of New Jersey placed a strange interpretation of that law that in his opinion would mean that a New Jersey resident would be breaking the law by obtaining the drug in another state because they would be breaking the law when they cross state lines. When other law makers and enforcers were asked their opinions of this new interpretation, they all stated that the decision made by the Attorney General of New Jersey was unconstitutional.

Nevertheless, we had to heed this interpretation and several hundred patients had to suddenly stop their therapy. We were required to indicate where the patients were sent to deal with their withdrawal symptoms and possible addiction. The answer was no one had evidence of addiction or withdrawal symptoms. The drug can be stopped suddenly without any consequences. Some patients were willing to just endure the decreased quality of life. Others were hoping to find another solution. Most who sought other physicians did not find an alternative treatment, and thus we began treating them with other dopamine agonists. One of these dopaminergic drugs was cabergoline and we had some success, but generally, it was not quite as good as dextroamphetamine [45-47]. Recently we found that carbidopa levodopa may be just as effective as the amphetamines, but more cases are needed to support this statement [48]. The biggest issue is that whereas so far there are no cases of women with Parkinson's disease taking carbidopa-levodopa who also became pregnant who had children with teratogenicity, there are not as many cases to be sure of the risk of taking this drug during pregnancy. Of course, a lot of our patients who have this increased cellular permeability syndrome also want to conceive as in the case described. Patients with this condition are also more prone to miscarriage, and we generally continue the drug throughout the first trimester. However, we stop it if the clinical manifestation of this disorder is likely to cease (e.g., dysmenorrhea), but continue the dopamine agonist to term if the clinical manifestations are severe and may return [41-43,49].

Since we have published more severe conditions than IBS associated with diarrhea and abdominal pain, including, ulcerative colitis, Crohn's disease, and microscopic colitis, and seemingly opposite conditions of severe gastroparesis, pseudo intestinal obstruction, and severe constipation, until recently we had never published any of our successful cases of treatment of IBS [41-43,50-56].

Prejudice against the use of dextroamphetamine has also permeated the concepts of physicians and pharmacists alike. A man with severe abdominal pain and marked cachexia with chronic pancreatitis was told by his medical team that death was imminent. The abdominal pain was unbearable despite being on high dosage opioids (a combination of oxycodone, OxyContin, and fentanyl). He was completely pain-free after eight months of treatment with dextroamphetamine sulfate given as amphetamine salts Not only did he gains 50 pounds back, he stopped all opiates at six months and was completely pain-free. Shockingly his pain management physician refused to take over his management and prescribe the dextroamphetamine sulfate [57]. He lives in Pennsylvania.

We have recently presented the case of a woman with severe gastroparesis refractory to standard therapy. For 10 years she was in constant pain but she also had exacerbations that required hospitalization multiple times per year. Though it took a very high dosage of amphetamine salts (150 mg/day) to provide total relief of pain, she had no side effects. Thus, the dopamine agonists were probably being over metabolized because she maintained a heart rate of 68. Nevertheless, for 20 years she was pain-free with normal bowel movements. However, her family physician kept encouraging her to stop the amphetamines, even though he had no alternative treatment plan. Her pharmacist retired, and the new one would not allow a dosage of more than 60 mg/day amphetamine salts. Within a few days of the reduced dosage, her mid-epigastric pain returned. Subsequently, she had an exacerbation that once again required hospital admission for this problem. On the higher dosage she did not have any exacerbations for 20 years. We kept her on the 60 mg per day of amphetamine salts but added carbidopa-levodopa 10/100 mg twice daily. She has now been pain-free for six months [58].

A male developed excruciating pain within minutes of finishing a meal and would have 25 episodes of vomiting per day. A foremost diagnostic and treatment facility in the United States diagnosed him with mesenteric sclerosis. They advised him that there was no treatment that is effective and that he would likely die in the near future from a perforated bowel. He was completely better within the first month of taking dextroamphetamine sulfate. He continues to do well now for 10 years [25]. He can eat any kind of food.

Another male had gastrocolic reflux which prevented him from finishing a meal without the need to defecate. This was completely abrogated by treatment with dextroamphetamine sulfate [25].

A 14-year-old female had severe mid epigastric pain after a short time during eating preventing her from finishing a meal. This was also completely mitigated by treatment with dextroamphetamine [59]. She also had diminished oocyte reserve. Quite interesting, the use of this dopamine agonist has been able to replete her ovarian reserve now that she is 16 as evidenced by increasing serum anti-Mullerian hormone levels [59]. Another woman with unexplained chronic intermittent lower abdominal pain quickly resolved after treatment with dextroamphetamine [60].

Despite no death, addiction, side effects requiring hospitalization, and no complaints to any governmental agencies, just recently the Pennsylvania government ordered us to stop prescribing amphetamines. We are planning to fight this. We are not aware of any reason why this edict was given. The state of New Jersey allows patients to go to drive-through dispensaries to receive medical marijuana or medical psychedelic mushrooms without even a physician consult. The state of Pennsylvania requires a telehealth visit by a physician to prescribe marijuana which usually lasts no more than 2 to 5 minutes.

The hope is that these case report reports will encourage other physicians to consider dopamine agonists for a variety of medical conditions, especially those that aren't responding well to standard therapy, or where standard therapy provides too much potential risk, expense or cost to the patient. Hopefully, if others share the same positive experience with dextroamphetamine sulfate or other dopamine agonists, they will publish case reports also. Of course, they should also be encouraged to publish any negative experience or failure to improve certain conditions with these drugs despite previous publications of positive results.

It is not clear what is the motive of governmental agencies making medical decisions that are contrary to the good health and well-being of the population. Nevertheless, if multiple physicians from various areas of the United States and other places in the world show the same beneficial findings, perhaps as a collective group, we can change the negative attitude about dextroamphetamine sulfate.

Alternatively, if fear of prescribing amphetamines prevents lack of widespread use of amphetamine, perhaps awareness of the positive benefit of dopamine agonists, we may find equal or better efficacy from other dopamine agonists e.g., carbidopa-levodopa, or other dopamine agonists. Perhaps with more reports of marked beneficial effects, a pharmaceutical company can develop an even more efficacious dopamine agonist with even fewer side effects.

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