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Dopamine agonists may be the best treatment for gastroparesis

Abstract

Gastroparesis is a dysmotility disorder where there is delayed gastric emptying not related to a mechanical obstruction. Milder cases can be treated by dietary changes and some pharmacological drugs, but standard therapy is considered at best fair. However, 30% have gastroparesis so severe that it is extremely debilitating and can lead to death. Unfortunately, there are not very effective standard pharmacological options for severe disease. There is presently a shift toward endoscopic surgical procedures which have limited success and surgical risks and expense. We present another case of marked highly effective, prolonged amelioration of severe medical treatment resistant gastroparesis with treatment with the dopamine agonist dextroamphetamine. There is a reason to believe that gastroparesis is one of the clinical manifestations of the increased cellular permeability syndrome. The mechanism of action of dopamine agonists is to prevent the infiltration of toxic elements into smooth muscle mitochondria causing dysmotility. Another advantage of using a dopamine agonist is that gastroparesis may be only one of the clinical manifestations of this disorder that are related to toxic elements infiltrating into various tissues across a mucosal barrier. In this case dextroamphetamine also ameliorated rapid weight gain from edema, dysmenorrhea, chronic fatigue, and headaches.

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Introduction

Based on studies of embryo implantation there is evidence that one of the important mechanisms to attract cellular immune cells, e.g., natural killer cells, macrophages, and cytotoxic T cells, into uterine tissue to create spiral arteries with a cell wall only one cell thick (needed to then allow nutrient exchange between mother and fetus), involves an autoimmune process. Studies suggest that Progesterone (P) suppresses dopamine thus increasing cellular permeability resulting in irritating elements crossing a mucosal barrier and attaching to certain designated thick-walled uterine arteries. This evokes a cellular immune response resulting in a stripping off of the thick cell wall of some of these thick-walled uterine arteries [1,2]. To reiterate one of the functions of dopamine is to decrease cellular permeability. There have been several reports of dopamine agonists used to decrease cellular permeability that has led to significant amelioration of chronic inflammatory disorders of the bowel and other abdominal organs [3-9].

Interestingly, dopamine agonists have also ameliorated long-term issues of muscle dysfunction. For example, dopamine agonists, e.g., dextroamphetamine sulfate has been able to improve symptoms of skeletal muscle dysfunction e.g., chronic fatigue syndrome, hereditary spastic paraplegia, and the mitochondria encephalopathy lactic acid stroke like syndrome [10-13].

Dopamine agonists have also provided great relief from smooth muscle disorders of the gastrointestinal tract, e.g., achalasia, pseudo intestinal obstruction, pathological constipation, and gastroparesis [14-18]. It has been hypothesized that the skeletal and smooth muscle dysfunction is caused by unwanted elements infusing into mitochondria causing muscle dysfunction [19].

Irritable Bowel Syndrome (IBS) with Diarrhea (IBS-D) is treated much differently than IBS with constipation (IBS-C) with one therapy aimed at decreasing bowel motility and the other increasing bowel motility. Recently we showed that dextroamphetamine sulfate was very effective for one woman with IBS-D and another woman with IBS-C despite their long-term failure to respond to other treatments [20]. Dextroamphetamine was highly effective for a woman with Mixed IBS (IBS-M) who had IBS-D 70% of the time and IBS-C 30% of the time [21]. The dopamine agonist was effective whether she was in the IBS-D phase or IBS-C phase [21].

The unwarranted negative attitude toward the use of amphetamines for the treatment of severe treatment refractory gastroparesis was the stimulating factor for writing another case report concerning gastroparesis. A woman that we reported before with very severe gastroparesis with constant abdominal pain and fullness but frequent and severe exacerbations that caused her to be admitted for hospitalization multiple times per year for a 10-year span had complete relief of the abdominal symptoms and no hospital admissions for 20 years while taking amphetamine salts. However, she required a very high dosage (150 mg/day) which provided her 94mg dextroamphetamine sulfate [18]. However, she had no side effects. A new pharmacist refused to fill the 150 mg prescription and insisted on a maximum of 60mg even though that dosage was not effective 20 years before. All of her symptoms returned and she had another exacerbation which necessitated her first hospitalization in 20 years. The pharmacist still refused to raise the dosage. The new case report showed that adding carbidopa levodopa 10/100 twice daily to the 60 mg amphetamine salts has returned her gastrointestinal status to normal again [22].

Thus, since there are only three cases in the literature showing how well this very disabling disease that is refractory to most conventional treatment options responds to dopamine agonist therapy, we decided to report a fourth case that has not only responded to dextroamphetamine but the benefit has been sustained over time [12,18,23].

Case report

A 44-year-old nurse consulted us for gastroparesis that was diagnosed by 3 different gastroenterologists. She initially presented to her first gastroenterologist 9 years before her visit to our practice because of abdominal pain and constipation with bowel movements of hard rock- like stools every 3 to 7 days. She had a consistent feeling of fullness and had early satiety. Gastroscopy and colonoscopy excluded obstruction. The diagnosis was confirmed by gastric emptying scintigraphy.

She was treated with fiber pills, docusate, domperidone 10 mg four times daily before meals, metoclopramide, probiotics, and ibergast®. They provided very little relief or improvement of her gastroparesis. She had been treated with these medications for about 1 year when she consulted our group.

Other clinical conditions included dysmenorrhea, irregular menses, rapid weight gain not explained by dietary intake, chronic fatigue, and headaches. However, the main pathological condition that bothered her was the gastroparesis especially the flares which lasted 2-3 weeks and were associated with unbearable pain

She was treated with dextroamphetamine sulfate 10 mg upon arising and noon. She noticed mild to moderate improvement in all of her symptoms. Finally, at 30 mg twice daily of amphetamine salts providing 37.6 mg dextroamphetamine all the gastrointestinal symptoms were gone and she had one painless bowel movement per day (she previously would take 30-45 minutes to pass the stool with a great deal of pain during the bowel movement that required a lot of straining).

At 60 mg per day of amphetamine salts providing 37.6 mg dextroamphetamine not only has her gastroparesis been successfully treated, but she does not have any headaches. Her dysmenorrhea was reduced to a minimal level, and her energy markedly improved. She was 68 inches tall and weighed 195 pounds. Her weight is now 161, which has been maintained for all of her 9 years of treatment with our group using dextroamphetamine sulfate. She is satisfied with the weight which was reduced while not changing her diet at all.

The only medications she ingests are dextroamphetamine sulfate and omeprazole which she takes for acid reflux. Her last blood pressure was 110/80 and her heart rate was 81 and regular at her last recent visit. She is presently 53 years old.

Discussion/Conclusion

The condition that we have named the “increased cellular permeability syndrome” is a very common problem especially, but not limited to women, that unfortunately is not well recognized by healthcare workers. It may only manifest as a single entity or more commonly may exist with other morbidities [1,24,25]. Thus, one of the main advantages of using dopamine agonists to treat certain pathological entities e.g., gastroparesis, is that many other comorbidities will also improve. This patient had rapid weight gain related to fluid retention, pelvic pain, headaches, and chronic fatigue which all improved with one extremely safe, well tolerated, and inexpensive medication. These other entities are also well known to respond to dopamine agonists, especially, but not limited to dextroamphetamine sulfate [26-38].

Duran et al. did a review entitled, “Gastroparesis for the non-gastroenterologist” [39]. The patient that we reported here, and the others that we have previously published, all had severe gastroparesis. We have treated many less severe cases with the same therapy, but we have never reported them. Even many severe cases, e.g., the one presented here, had never been previously reported. For years, physicians have been influenced by the need for randomized controlled trials to determine treatment strategy. These usually require a great financial investment that generally will be initiated by a large pharmacological company who, for the most part, are hoping to get a new brand drug approved.

To promulgate information about the efficacy of an off-label use of the generic drug, the best method to pass forward this information is to publish a small series. Alternatively, one could find a severe case of a clinical entity, and not only show quick efficacy with the alternative drug, despite failure with prior therapy, but also show long-term efficacy of that drug. This would be especially important where the standard less effective drug had significant long-term or short-term risks or generate a greater expense. We believe that we fulfilled this criterion in the case reported here.

The case reported here and the others that we have reported required several hospitalizations with the aforementioned exacerbations of gastroparesis. The hospitalization required, intravenous hydration, and nasoenteric decompression, and in some circumstances may even require total parenteral nutrition

for a short time.

Interestingly one of the many standard therapies (but generally not very effective) are a class of drugs known as prokinetics. These include the only one approved for the treatment of gastroparesis in the United States and that is metoclopramide which was used to treat the patient presented here. Interestingly both metoclopramide and domperidone are dopamine antagonists, whereas dextroamphetamine sulfate is a dopamine agonist.

Dextroamphetamine sulfate is considered a sympathomimetic amine. Thus, although it releases dopamine from the sympathetic nerve fibers (and is thus a dopamine agonist), it also releases epinephrine and norepinephrine. Thus, it is theoretically possible that the benefit was from catecholamine increase rather than dopamine, or the two chemicals could be working together. However, favoring the concept that it is all related to increasing dopamine is the fact that in the recent case already reported which showed a marked beneficial effect of adding carbidopa levodopa to the reduction of the high dosage of dextroamphetamine thus supporting the concept that activating the release of dopamine is the mechanism by which dextroamphetamine sulfate improves gastroparesis [22].

The patient described in the present case report also failed with another dopamine receptor antagonist domperidone. She went to another country to acquire it because it is not approved for treating gastroparesis in the United States but is preferred by many gastroenterologists or other types of clinicians treating this disorder in Europe and Asia because it does not cross the blood brain barrier. Thus, it does not cause certain neurologic side effects that can happen when taking the only approved drug in the United States, metoclopramide [40]. The reason why domperidone is not approved in the United States is related to it causing in some cases a relative prolongation of the QTC interval on the electrocardiogram [41].

A more recent update on various other types of pharmaceutical medications that have been used to treat gastroparesis has been recently provided [22]. However, there has been a new paradigm shift in gastroparesis management [42]. This shift may only refer to the 30% of patients who do not adequately respond to nutritional modifications and pharmaceutical drugs [42]. Of course, this number could be even smaller if dopamine agonists were included in the treatment of mild forms of gastroparesis. There is a good probability that even the majority group that would not be at the extreme level of the case presented here and even the aforementioned recent case report might still find dopamine agonists more effective and with less side effects than the antiemetic and prokinetic medications.

The new shift in management seems toward surgical management is based on the fact that one of the main pathophysiologic conditions leading to gastroparesis is pyloric dysfunction. This dysfunction causes a defect in gastric emptying and pyloric clearance [43,44]. This has led to multiple types of endoscopic therapies, including intramuscular pyloric botulinum injection pyloric dilation, transpyloric stenting, and gastric peroral endoscopic pyloromyotomy (G-POEM) [45-51]. One of the aims of publishing these case reports regarding dopamine agonists, and many other recent reports in different organ systems, is to increase the awareness of physicians and scientists around the world to be aware that the etiologic basis of many chronic illnesses, that frequently do not have a very effective relatively risk free treatment at present, is the inability of the mucosal barrier of the tissue in various parts of the body to preclude the transudation of various inflammatory agents that can also cause functional impairment. Perhaps scientists and pharmaceutical companies can now, armed with this information, develop even better dopamine agonists or find a better way to correct the increased cellular permeability syndrome than dopamine agonists.

However, it takes many years to bring a drug to the pharmaceutical market. In the meantime, in our opinion, the best therapy for gastroparesis is the dopamine agonist, dextroamphetamine sulfate or lisdexamfetamine. With at least 50 years of treating a large variety of chronic treatment refractory cases that involve hundreds of patients and thousands of patient's years of treatment we can honestly state that 1) the drug ameliorates most of these treatment refractory conditions. 2) There are no serious long-term side effects or subsequent development of cancer as seen with many of the treatments that dextroamphetamine replaced e.g., corticosteroids or tumor necrosis factor alpha inhibitors. 3) Most patients tolerate the drug well. Some minority need to stop related for persistent insomnia (short term not rare, but usually dissipates in 2-3 days without hypnotics). However, no one has ever been hospitalized because of a side effect or died from a drug complication related to use of dextroamphetamine. 4) No one has ever become addicted no matter how long they were taking the drug. 5) There are no withdrawal symptoms in the dosages used despite sudden cessation as we sometimes do in pregnant women after they finish the 1st trimester if the main reason for taking amphetamines was for pelvic pain or infertility or recurrent miscarriage. However, if there are other symptoms that exist in other organ systems, then the drug is continued to term [5,6,17,52,53]. Probably the most frequent event that enables us is to make a statement about lack of withdrawal side effects with sudden cessation is that patients run out of dextroamphetamine frequently related to shortages.

These shortages of amphetamine salts are partly related to their class II narcotic restriction (placed in the same category as fentanyl)! We must remember that they are prescribed commonly for children and adolescents with attention deficit hyperactivity disorder. The hope is that if these publications evoke an interest in other clinicians to try this therapy, and if they share our very positive perception of its efficacy and safety perhaps as a group, we will convince the federal or state governments to remove the narcotic restriction altogether or down grade it to a lesser restriction category.

Unfortunately, despite this increase in very positive case reports, governmental agencies seem to be trying harder to prevent its use. The state of New Jersey, which is the location of our medical school had an unusual law for many years that precludes a physician from prescribing a drug with a class II narcotic restriction for an off-label use. Thus, for many years for patients who we thought would benefit from dextroamphetamine for their clinical problem but lived in New Jersy we did their evaluation in Pennsylvanian, a state that has no such law.

However, in 2021, the Attorney General at that time made an interpretation of the law differently than his predecessors that precludes a patient from obtaining the drug off-label from another state because they would be breaking the law when they enter New Jersey with the drug and so would the physician be breaking the law who prescribed it. The attorney general

also sent a reminder that amphetamines in the state of New Jersey can only be prescribed by psychiatrists, neurologists, and family physicians, and thus could not be prescribed by gynecologists or internal medical specialists. Seeking opinions from other lawmakers even from New Jersey, they consider that interpretation of the New Jersey law as unconstitutional.

However, if we want to take something positive from the experience of so many New Jersey patients suffering once again from their various morbidities was that the New Jersey Attorney General office required a listing of all the patients who had drug withdrawal symptoms and in what facility were they treated for addiction? The answer was none despite the sudden cessation of this drug even people taking it for many years. It is so confusing why the state of New Jersey, and probably some other states, seem to have such an extreme negative view of this drug.

But another positive experience from the prohibition of amphetamines to the majority of people who have the increased cellular permeability syndrome is that they can try other dopamine agonist drugs and they too have been showing efficacy. Interestingly, we would have been hesitant to try carbidopa-levodopa on a patient with gastroparesis with frequent nausea and vomiting when a large majority of patients treated for Parkinson's disease complain of nausea and vomiting at least for the first couple weeks. However, because the pharmacist refused to allow one patient treated with high dosage (150 mg) but well tolerated amphetamine salts with a great success for 20 years allowing only 60mg/day total we had the opportunity to show that adding a different dopamine agonist with no narcotic restriction, i.e., carbidopa-levodopa 10/100 mg twice daily to 60 mg amphetamine salts, proved effective with no symptoms for 6 months [22,54].

The impetus to intensify publication of cases reported relevant to the beneficial action of dopamine agonists for gastroparesis and other morbidities is driven by a recent personal tragic event. Dopaminergic agonists have been shown in a case report to be beneficial for a dermatological disorder called pyoderma gangrenosum [55]. A 51-year-old woman with a history of rheumatoid arthritis had severe local reactions to the Tumor Necrosis Factor alpha (TNF alpha) inhibitor drugs etanercept and adalimumab. The dermatologist from a foremost university medical center prescribed infliximab. This caused disseminated microvascular thrombosis with excruciating bilateral leg pain, acute renal failure, probably from bilateral renal artery thrombosis, and stroke. Furthermore, it caused immune suppression so that despite intravenous infusions of multiple antibacterial drugs, antiviral drugs, and antifungal drugs she died from nosocomial infection [56]. Unfortunately, this patient was the daughter-in-law of the 1st two authors of this case report. Had the dermatologist been aware of the marked benefit of using dopamine agonists for treating a large variety of dermatologic disorders he would not have taken the risk of using another TNF alpha inhibitor, knowing of her previous adverse events from treatment with 2 other TNF alpha inhibitors. The cost of amphetamine salts is no more than $50 per month and TNF alpha inhibitor drugs could be 400-500 thousand dollars per year.

Besides the risks or side effects of the various standard pharmacological options for gastroparesis, surgical options are certainly not a panacea and present with the risks of surgery and subsequent complications. Certainly, considering risk/benefit ratios, this favors the use of dopamine agonists as first line therapy with possibly dextroamphetamine sulfate as the best dopamine agonist option available at present.

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