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The relative efficacy of three different dopamine agonists in relieving symptoms of various manifestations of the increased cellular permeability syndrome: Case report

Abstract

There is evidence that a high percentage of chronic medical disorders have as the initiating etiology a defect in the mucosal barrier of a given tissue leading to infiltration of unwanted toxic elements which results in inflammation pain or organ dysfunction related to unwanted elements altering mitochondria or nerve pathways. Dopamine functions to decrease cellular permeability. Indeed, dopamine agonists have been found to frequently ameliorate the symptoms of these disorders better than conventional therapy. Collectively, these conditions are part of the increased cellular permeability syndrome. For the past 40 plus years, the main dopamine agent used to treat has been Dextroamphetamine Sulfate (DS). Even though DS is non-addicting when used in pharmacological dosages, can be suddenly stopped without weaning, and is frequently not only more effective than conventional therapy but has a much greater safety profile, it has a class II narcotic restriction. Instead of removing the class II restriction, there has been a move to inhibit physicians from prescribing DS and thus a good time to try other dopaminergic agonists. A woman with 3 manifestations of this increased cellular permeability syndrome, i.e. severe headaches, severe chronic regional pain syndrome, and constant twitching of one eyelid had almost total relief of all 3 of these disorders following DS therapy. After 8 years of stability, the interpretation of a New Jersey law was changed precluding its use. Though cabergoline was about as effective for DS for headaches, it didn't help the CRPS and eyelid twitching. Carbidopa levodopa eradicated all 3 entities.

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Introduction

Studies of steps needed for embryo implantation have suggested that there is a need to create thin-walled spiral arteries from early luteal phase to delivery, to allow nutrient exchange between mother and fetus [1]. Neovascularization is a slow genomic process involving the nucleus. The appearance of these vessels that are only one cell thick, from cells shed from the extra villus trophoblast appear too quickly to be explained by neovascularization [1]. Remodeling the thick-walled uterine arteries by autoimmunity stripping off the cell wall of these vessels would seem to be more practical.

Some data suggest that the mechanism to evoke a cellular immune response in the luteal phase is by progesterone (P) blocking the effect of dopamine which normally functions to decrease cellular permeability [1,2]. According to this model, the increase in cellular permeability allows the infusion of irritants into pelvic tissues causing a cellular immune inflammatory response leading to autoimmune removal of the thick cell walls of the uterine arteries found in the proliferative phase creating thin-walled spiral arteries.

The Natural Killer (NK) cells (70%) macrophages (20%) and cytotoxic T cells (10%) that are markedly increased in the luteal phase, and are especially found in the fetal-placental

microenvironment must be neutralized in their killing activity before day 6 after ovulation when the fetal-placental unit invades the endometrium [2]. This is mostly accomplished, according to this model of successful embryo implantation, by P activating Membrane Progesterone Receptors (mPRs) to make certain immunomodulatory proteins e.g., the Progesterone Induced Blocking Factor (PIBF) and the progesterone receptor membrane component-1 protein which negates the killing activity of these cellular immune cells [3].

An extension of this model is that under normal inflammatory condition, women have no symptomology but with excessive permeability with unwanted irritants in excess traversing the mucosal barrier pelvic pain might ensue of various types including chronic pelvic pain, mittelschmerz, dyspareunia, and dysmenorrhea [4]. The basis of this model was hypothesized based on experimental data over 45 years ago. It soon became clear that there were other co-morbidities that were seen concomitantly with the pelvic pain syndrome.

If this hypothesis was correct them theoretically treating with drugs that release more dopamine e.g., the sympathomimetic amine dextroamphetamine sulfate and its derivatives (so called sympathomimetic amines because it releases other biogenic amines from sympathetic nerve fibers e.g., norepinephrine and epinephrine) or more pure agonists e.g., levodopa carbidopa, should relieve various types of pelvic pain. Bromocriptine had not yet made it to the pharmaceutical market but was available for galactorrhea or prolactinomas experimentally (CB-154).

Related to side effects seen in patients with Parkinson's disease e.g., nausea and vomiting (at least initially) and tardive dyskinesia (more often in higher dosages) it was decided to use the anti-depressant and drug for treating Attention Deficit/Hyperactivity syndrome (ADHD) in children dextroamphetamine sulfate.

Fifty years ago, case reports were not considered as the same scientific merit as randomized controlled trials or matched controlled studies. Though clinical experience was showing marked benefit for a variety of different types of pain syndromes with dextroamphetamine treatment, the first published case report by our group on pelvic pain, in this case of bladder origin, i.e., interstitial cystitis, was not published until 2005 [5]. In fact, the first case report of treating severe chronic pelvic pain was not until 2007 [6]. Interestingly, the first case report from our group demonstrating the marked clinical benefits from dextroamphetamine sulfate was from a clinical allergist who referred a patient covered with urticaria almost constantly for seven years who was interested in assisted suicide because no treatment gave her relief. Treatment with dextroamphetamine sulfate resulted in complete disappearance of the urticaria within one week, which never returned until 25 years later when she was off the drug for one month. They disappeared again with the resumption of the amphetamine. There were no withdrawal symptoms from sudden cessation of the drug except for full blown return of her urticaria. The case report was published in 1984 after a referred second case who also markedly improved with this drug [7].

Subsequently there have been many case reports showing marked amelioration of every type of pelvic pain (too many to report) but many of them have been summarized in some reviews on pelvic pain and endometriosis especially how this-therapy can also improve fecundity [8-12].

Sometimes, as mentioned, there may be other pathological conditions because of weakened tissues in different body locations that also improve when dextroamphetamine is used for pelvic pain, e.g., Crohn's Disease [4]. This condition has been named the increased cellular permeability syndrome [13]. Various types of inflammatory bowel disease may exist without pelvic pain yet similarly show marked improvement with dextroamphetamine treatment [14-19].

Headaches have been associated with a variety of different types of pelvic pain and were shown to have marked pain relief along with the pelvic pain following treatment with dextroamphetamine [20]. However just as seen with inflammatory bowel disease there have been many case reports of various types of headache pain without any other pain in women that have had marked improvement with dextroamphetamine therapy despite failing conventional therapy [20-26].

Though the increased cellular permeability syndrome is more common in women it is also found in men who also respond well to the dopamine agonist dextroamphetamine [27]. Some very severe cases of males with severe headaches who responded extremely well to amphetamine therapy without any clinical benefit from standard or conventional therapy are de- scribed in this publication [27].

It is not clear how dextroamphetamine can be placed in the same category of drugs as dangerous opiates e.g., fentanyl, yet it is described as having a high safety profile, is non-addicting when used in pharmacologic dosages, and can even be stopped suddenly without weaning with no withdrawal symptoms, This class II restriction makes its availability low and seems to carry an onerous reputation amongst pharmacists and many doctors alike and healthcare insurance companies. With the war against dangerous very addictive opiates, somehow dextroamphetamine is linked with these opiates, and it is quite difficult at present for patients to obtain the medication. Some states in the United States restrict its prescribing to only psychiatrists and neurologists.

This seems to be a good time to try other dopamine agonists that have no class II restrictions and are thus more attainable and similarly effective as generic dextroamphetamine sulfate. They are also available as generic and are inexpensive.

Going back to 50 years ago the 3 drugs considered as dopamine agonists were dextroamphetamine, levodopa carbidopa, or CB154 which became bromocriptine which morphed into the more popular cabergoline. The case presented here will describe the relative efficacy of dextroamphetamine sulfate, cabergoline, and levodopa carbidopa in a woman with a long history of severe headaches. Several severe manifestations of the increased cellular permeability syndrome included reflex sympathetic dystrophy, edema of her feet, ankles and legs along with constant twitching, and muscle spasm of the left eye.

Case report

A 25-year-old woman began having migraine headaches which were considered by the patient as both severe and debilitating. Initially she only had one per week but when they increased to 4 per week. She consulted many physicians but eventually was treated by a headache clinic at a university medical center. Though she was prescribed propranolol, verapamil, pregabalin, gabapentin, and carbamazepine, the amount of relief she received from these drugs were only transient and she stopped because the side effects outweighed the benefits.

The headaches persisted until age 42 when she fell and strained some ligaments in her left ankle. Though by magnetic resonance imaging the injury seemed to heal, the pain and swelling in her left foot, ankle and leg persisted. After consulting a couple neurologists, the conclusion was that she was suffering from chronic Complex Regional Pain Syndrome (CRPS) otherwise known as (reflex sympathetic dystrophy) and one of the suggested treatments was ketamine.

She consulted our medical practice to get a second opinion. We suggested treatment with dextroamphetamine sulfate. The dosage was gradually increased to 90 mg/day of the immediate release tablet. Not only did her CRPS and edema completely resolve but so did her migraine headaches.

Prior to being treated with dextroamphetamine she developed a herpes zoster infection with the rash above, but close to her left eye. She was treated with valacyclovir, but the pain persisted for several months.

She subsequently developed Bell's Palsy with drooping of her left side of her mouth and her left eye. Eventually the drooping resolved (she was treated again with valacyclovir), but she had a residual constant twitching of her left eyelid both day and night and painful muscle spasm of the extraocular muscles. Not only did the migraine headaches and the pain from CRPS markedly improve, but so did the eyelid twitch and the muscle spasm of the left eye.

There was a law in the state of New Jersey that did not allow a physician to prescribe a class II drug off label. Since she did not have attention deficit disorder (ADD), she had to come to our office in Pennsylvania rather than our office in New Jersey where she lived. She continued her marked amelioration of the migraines, CRPS, eyelid twitching, and the foot and leg edema for 8 years when the attorney general of New Jersey placed his interpretation of the law in New Jersey to also mean that a person from New Jersey could not receive a prescription for a class II drug from another state because when she would reenter the state she would be, in his opinion, breaking the law. He further interpreted the law that the physician writing the prescription knowing she lived in New Jersey would also be breaking the law.

Though our thoughts and the view of many other physicians and even a former attorney general of another state that his interpretation was unconstitutional, nevertheless we had no choice but to comply to the law and stop writing the prescription for amphetamine salts 90 mg containing 56.4 mg dextroamphetamine sulfate.

She consulted a neurologist in Pennsylvania who did not also have a license in New Jersey hoping that physician would prescribe the dextroamphetamine for her since the New Jersey attorney general would not have the power to prosecute a physician from another state. Instead, the neurologist wanted to try to treat the patient with one of the new generation of drugs for migraines that target the calcitonin gene-related peptide. She did not have much improvement of her headaches following treatment with galcanexumab nor nomegepant or ubrogepant. Her CRPS returned as did her constant eye twitching.

She reconsulted our group to see if there were any therapies besides dextroamphetamine that could be prescribed to a New Jersey resident. We placed her on a different dopaminergic drug that has no narcotic restriction named cabergoline that is approved to treat galactorrhea or prolactin secreting tumors. The dosage was gradually increased to 0.5 mg three times per week. This dosage relieved her headaches almost to the same degree as amphetamine. However, she did not gain any relief from her CRPS or constant eye twitching.

She stayed on the cabergoline for 2 years with the headaches markedly reduced in frequency and intensity but no relief in the CRPS or constant eye twitches. She again consulted us to see if there were any new treatments for the CRPS or eye twitching. She had stated when she knew that she would no longer be able to be prescribed dextroamphetamine, she saved her last bottle for "special occasions" and stated that whenever she would take the amphetamine her eyelid twitching would stop, and she would gain relief in her leg pain.

The patient was started on carbidopa/levodopa 10 mg/100 mg two times per day. She had significant nausea but no vomiting. She had stopped the cabergoline. The nausea dissipated after two weeks. The headaches were completely prevented in this dosage, and she had about 70% improvement in the CRPS and eyelid twitching. Her dosage after 6 weeks was increased to 10 mg/100 mg three times per day, and she states that she has had 98% improvement in the headaches, RSD, and eyelid twitching and leg edema. She has shown persistent symptom relief for 6 months.

Discussion

Dextroamphetamine sulfate has been shown to also ameliorate pain from CRPS that was resistant to other therapies [28]. Cabergoline can be effective for various manifestations of the increased permeability syndrome besides headaches seen in this case including pelvic pain and pain from carpel tunnel syndrome [29,30]. However, our experience with stopping dextro- amphetamine sulfate in all patients living in New Jersey despite feeling so well by orders from the attorney general of New Jersey, that the relief with cabergoline was still inferior to that provided by dextro- amphetamine sulfate, similar to this case reported.

With now a greater emphasis at present worldwide to try to limit the use of opiates according to discussion with legal counsel in the healthcare industry, it would appear that many pain management physicians were now willing to switch their patients to dextroamphetamine. However, the supply is limited because at least in the United States a pharmacy cannot dispense class II drugs more than 20% of the total non-class II drugs that are dispensed.

Interestingly, there is apparently the same type of law in California that precludes a physician from dispensing a class II drug off-label. The attorney general of California required a meeting with a pain management physician in California who never was cited for any improprieties for prescribing opiates. The attorney general told him to stop prescribing dextroamphetamine despite the fact that the physician stated that this was the most effective drug for various pain conditions that he has even found and there were very few side effects, no withdrawal complications for sudden stoppage, and no evidence of addiction in the pharmacologic dosages that are prescribed. That physician informed the attorney general that without the use of opiates and without the use of superior amphetamine therapy, the patients with pain will suffer without any other treatment option. Thus, he refused to stop prescribing dextroamphetamine. The attorney general suspended his medical license.

We have reported cases of how patients with severe pain despite high dosage opiates not only had almost total relief with taking dextroamphetamine but were able to stop the high dosage of opiates without any addiction. One man, an ex-marine had multiple bone fractures related to damage from an improvised exploding device in the Gulf War. Though they did not think he would survive but he did. However, despite 5 surgeries he was left with almost total body pain with the back the worst that was not relieved.

Not only was most of his pain completely relieved after one month of dextroamphetamine, but he was also able to stop the opiates suddenly without withdrawal. He continued his relative pain-free existence now for 10 years [27]. Another man was considered terminal related to chronic pancreatitis with severe pain not alleviated even slightly by high dosage opiate. Dextroamphetamine was added to the opiates and gradually decreased. He was pain free at 8 months on 90mg amphetamine salts but had been completely off opiates after 6 months. He gained 50 pounds in 6 months, and his good health has continued for 8 years [31].

An 89-year-old male with severe post herpetic pain did not respond to any therapy and had so little relief despite high dosage opiates was pain free after 1 month of amphetamine therapy. He died peacefully in his sleep at 94 [32].

The cost of health care is rising precipitously at least partially related to money spent to create new drugs to improve various medical conditions. However, it takes about 3 billion dollars to get a new drug to the pharmaceutical market. Thus, the reimbursement is extremely high, which in turn causes the cost of healthcare to skyrocket. There are many drugs that are now generics that could be repurposed which would markedly reduce the cost of healthcare, yet for some unknown reason there seems to be opposition to treating with amphetamines despite the demonstration of marked efficacy and safety in various case reports.

Those opposing the use of amphetamines seem to be working to limit its use rather than say that amphetamine is soon to be universally utilized. Thus, we must look for alternatives that are just as effective, just as inexpensive, and with reasonable side effects. The demonstrated benefit of cabergoline helps support the concept of the critical role of relative dopamine deficiency in the etiology of a very large number of seemingly unrelated chronic medical conditions. However, it seems to be somewhat inferior to dextroamphetamine as shown in this case and in personal experience.

Thus, the question argues as to whether the release of other biogenic amines from sympathetic nerve fibers by dextroamphetamine e.g., norepinephrine may also work in conjunction with the increase in dopamine. The case showed that the pure dopamine agonist levodopa carbidopa ameliorated the various multiple severe symptoms. We will be conducting other studies to evaluate the efficacy vs side effects of levodopa carbidopa in patients with the increased cellular permeability syndrome.

Dextroamphetamine sulfate has had very good success in treating vulvodynia [33-36]. Women with neurological conditions e.g., Parkinson's disease have a high frequency of vulvodynia [37]. Interestingly many years ago Ford et al found that the treatment of Parkinson's disease by levodopa carbidopa completely ameliorated the associated vulvodynia [38].

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