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Review Article

Dopamine Agonists Aiding in Successful Follicular Development and two Live Deliveries Despite Premature Ovarian Failure and Ameliorating Severe Vaginal Pain

Jerome H Check[1,2]* and Ann DiAntonio BSMT[2]

[1]*Cooper Medical School of Rowan University, Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology & Infertility, Camden, NJ, USA*

[2]*Cooper Institute for Reproductive Hormonal Disorders, P.C. Mt. Laurel, NJ, USA*

***Corresponding author:** Jerome H Check, Cooper Medical School of Rowan University, Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology & Infertility, Camden, NJ, USA

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Abstract

A technique has been developed that allows the restoration of FSH receptors on granulosa theca cells of antral follicles in women who appear to be in ovarian failure thus restoring sensitivity of the follicle to FSH. This can allow the development of a dominant follicle with subsequent ovulation and even live deliveries. A woman who appeared to be in premature menopause attained a mature follicle three of three times by lowering her chronically elevated FSH levels with ethinyl estradiol which enabled an extraction of 3 metaphase II eggs and all fertilize. Intracytoplasmic sperm injection (ICSI) was performed because of oligoasthenozoospermia resulting in 3 day 3 embryos which resulted in 2 live deliveries from 2 embryo transfers. The successful pregnancy may have been aided by the use of the dopaminergic drug dextroamphetamine sulfate which also markedly ameliorated her dysmenorrhea, chronic failure, and headaches. Related to shortages of the class II drug dextroamphetamine, and an unwarranted misunderstanding by law makers and physicians alike, the drug was stopped. She developed a severe constant burning of the vagina. However, in contrast to dyspareunia, there was no discomfort with intercourse on bimanual examination. There was also no evidence of infection to cause this unbearable knife-like constant vaginal pain. The pain, however, was completely abrogated by the use of another dopamine agonist, cabergoline. This is the second reported case report of treating constant vaginal pain (rather than abdominal or pelvic pain) with a dopamine agonist and the first one aided by the use of cabergoline.

Keywords: Vaginal Pain; Premature Ovarian Failure; Ethinyl Estradiol; FSH Receptor Upregulation; Increased Cellular Permeability; Dopamine Agonists; Cabergoline

Introduction

In 1984 a technique was described which has been called by the authors as the FSH receptor up-regulation technique that enabled some women considered to be in overt menopause to not only ovulate but achieve live deliveries naturally without the aid of in vitro fertilization [1]. By 1990 the same authors shared their experience with this type of follicular maturation technique in 100 consecutive women with apparent menopause allowing 35% to ovulate at least once in 4 treatment cycles with a 20% conception rate and a 10% live delivered pregnancy rate [2]. These pregnancies were natural without in vitro fertilization embryo transfer (IVF-ET). There was no restriction for age or length of time in ovarian failure before treatment was rendered [2]. Nevertheless, the group ovulating and/or conceiving were younger with less length of time in menopause than those who were not successful [2]. Many of these women had serum FSH levels over 100 mIU/ml. There were, and still are, some successes with women in menopause using their own eggs and conceiving naturally who are of advanced reproductive age [3].

The basic tenet of the FSH receptor up-regulation technique is that there are some women who have constant hyper gonadotropic hypogonadism with marked estrogen deficiency who do convert a primordial follicle to a primary follicle, which does advance to the antral stage, where gonadotropin stimulation would allow follicular progression to the dominant follicle stage except that the chronically elevated levels of FSH has caused a reciprocal down regulation of FSH receptors to prevent cell burnout [4-7]. Though suppression of high serum FSH levels can be achieved by treating with a gonadotropin releasing hormone agonist (GNRH-a) or antagonist (GNRHant) the much less expensive option is to

reduce serum FSH levels by negative feedback to the pituitary with estrogen suppression. The preferred type of estrogen is ethinyl estradiol mostly because it does not register in the serum assay for estradiol (EE), and it is sufficiently potent to lower serum FSH with just one pill daily [8].

In the absence of surgical damage to the ovaries or egg depletion from chemotherapy or radiation therapy, the most common cause of diminished ovarian reserve (DOR) or premature ovarian failure (POF) is autoimmune damage. One hypothesis as to the nature of the autoimmune mechanism leading to oocyte destruction is an exaggeration of the inflammatory process required during the luteal phase to create thin-walled spiral arteries from autoimmune remodeling of some of the thick-walled uterine arteries [9,10].

One tenet of the hypothetical model that suggests inflammation is needed for appropriate implantation is that the mechanism of induction of the inflammatory process involves progesterone (P) blocking the effect of dopamine on decreasing cellular permeability [9,10]. Following the autoimmune removal of the thick cell walls it is necessary to negate the natural killer (NK) cells, macrophages, and cytotoxic t-cells found in the fetal placental microenvironment from attacking the fetal semi-allograft. Suppression of the subsequent cellular immune reaction is accomplished, according to this model, by P activating membrane progesterone receptors (mPRs) to secrete immunomodulatory proteins e.g., the progesterone induced blocking factor (PBIF) which negates the killing activity of these cellular immune cells [11-13].

Normal amount of inflammation for procreation is frequently not associated with pelvic pain. However, excessive pelvic pain may be a sign of excessive inflammation, which may lead to rejection of the fetal semi-allograft. Sometimes the supplementation of extra P, especially by vaginal or intramuscular route, may be sufficient to increase the secretion of immunomodulatory proteins e.g., PIBF, or the progesterone receptor membrane component-1 (PGRMC-1) protein to sufficiently negate the embryo or fetal immune rejection and thus correct infertility or prevent miscarriage [13-16].

However, sometimes the degree of inflammation is too great to be suppressed by the increase in secretion of P induced immunomodulatory proteins. One can negate the above supranormal inflammatory effect by treating the woman with a drug that releases more dopamine from sympathetic nerve fibers e.g., dextroamphetamine sulfate (DS) or cabergoline or treat with dopamine itself e.g., carbidopa levodopa [17,18].

Evidence of the efficacy of dopamine agonists in helping fecundity is difficult to prove because many other corrective measures are frequently occurring at the same time. Suggestive benefits are mostly provided by anecdotal cases e.g., successful live delivery when adding dextroamphetamine to the treatment regimen in a woman with previous multiple miscarriages following IVF-ET despite aggressive P therapy from early luteal phase [19].

There are many anecdotal case reports and small series leaving no doubt that dopamine agonists can effectively ameliorate various types of pelvic pain including dysmenorrhea, mittleschmertz, chronic pelvic pain, and pelvic pain of the bladder organ i.e., interstitial cystitis [20-30].

All of the above references to case reports using dopamine agonists to relieve pelvic pain have used the dopaminergic drug dextroamphetamine or lisdexamphetamine. Dextroamphetamine is actually a sympathomimetic amine that efficiently releases dopamine but also epinephrine and norepinephrine. Thus, though the original reason for trying this drug for chronic pain and correction of autoimmune infertility or recurrent miscarriage was its efficacy in increasing dopamine one could argue that it is possibly norepinephrine or epinephrine or their interaction with dopamine that provides the beneficial effect.

Amphetamines have proven to be highly effective for ameliorating pelvic pain, and probably infertility, but also a large number of other chronic or pathological disorders not just in women, but also in men [31-34]. In the dosages used, the drug is non-addicting, can be stopped suddenly with no withdrawal or adverse events, it is highly effective when other much riskier and much more expensive drugs considered standard for the condition have failed, and very safe to be given during pregnancy. Nevertheless, for some unknown reason amphetamines have a class II narcotic restriction which limits their availability. Also, like all drugs, sometimes there can be a side effect that prevents the use of amphetamines to treat a certain condition. Sometimes the side effect is more toward the release of catecholamine.

Dopamine agonists that do not release catecholamines have also demonstrated efficacy in anecdotal cases for dysmenorrhea and chronic pelvic pain, chronic headaches, chronic regional pain syndrome, and carpal tunnel syndrome [35-38].

A case is presented of a woman with premature ovarian failure, and pelvic pain who utilized the FSH receptor up-regulation technique to induce ovulation leading to two live deliveries in which one dopamine agonist, dextroamphetamine sulfate, was used to ameliorate her pelvic pain, and probably aided her in the two successful pregnancies. However, because of a new interpretation of a state law, she was no longer able to be treated with dextroamphetamine off-label and her pelvic pain returned. However, instead of a return of the severe dysmenorrhea upon stopping dextroamphetamine it was replaced by a constant burning vaginal pain. The effect of using another dopamine agonist cabergoline will be discussed.

Case Report

The patient first consulted our practice at age 29 with secondary amenorrhea. Based on a history of 2 years of amenorrhea and undetectable serum anti-mullerian hormone levels x2, serum FSH levels over 100mIU/nl x3, and serum estradiol(E2) less than 15pg/nl, she was diagnosed with premature ovarian failure (POF).

The woman had very severe dysmenorrhea as a teenager that would be so incapacitating that she frequently had to stay home and not go to school. In her late teens, she was prescribed oral contraceptives which improved the dysmenorrhea so that the

pain was not incapacitating, but did require nonsteroidal anti-inflammatory drugs for the first 2 days of menses.

She stopped oral contraceptives at age 28 for the purpose of trying to become pregnant. She had amenorrhea for one year when she consulted our practice of reproductive endocrinology and infertility. Prior to our consult, she had two other consults with different infertility specialists who advised her that her only option for pregnancy was to use donor eggs.

She heard that we had experience in achieving ovulation despite hypergonadotropic amenorrhea with estrogen deficiency, and also successful pregnancies. At that time, her husband also had oligoasthenzoospermia. Thus, we advised her that if we develop a mature dominant follicle that her best success would be with in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI).

Since she had amenorrhea, she did not have dysmenorrhea at this time. However, she was suffering from severe fatigue and migraine headaches. We advised her that her history of dysmenorrhea and POF are part of an autoimmune generalized condition more common in women, but also present males which has been termed the increased cellular permeability syndrome [32-34,39]. These disorders can be corrected by treating with dopaminergic drugs. However, this condition untreated could lead to immune rejection of the fetus, leading to failure to conceive or miscarriage [17-19,40-42].

Thus, we advised the patient that while we are trying to restore down-regulated FSH receptors on her granulosa-theca cells in the hopefully few remaining follicles by lowering her chronically elevated serum FSH levels by using ethinyl estradiol, we should start her on the dopaminergic drug dextroamphetamine sulfate, the dopaminergic drug with which we have had the most experience and also a drug with a good safety record for lack of birth defects [43,44]. She would need to take it at least through the first trimester. In fact, our goal would be to titrate the dosage of dextroamphetamine sulfate to the level that would correct or markedly ameliorate her chronic fatigue syndrome and headaches, which were likely to respond to amphetamine therapy since dextroamphetamine releases dopamine from sympathetic nerve fibers, (along with epinephrine and norepinephrine) and treatment with this drug has immensely ameliorated both chronic fatigue syndrome and headaches, even though they had been resistant to other therapies [45-52]. She also improved her mild to moderate attention deficit disorder (ADD).

The dextroamphetamine was given as amphetamine salts. Fifteen mg of amphetamine salts provides 9.4 mg of the active ingredient dextroamphetamine sulfate. Three prescriptions were written for the immediate release tablets 15 mg upon arising and noon, 20 mg a.m. and noon, and 30 mg a.m. and noon each for 30 days. If a smaller dosage corrected the problem, the increased dosage could be avoided if not preferred by the patient by breaking the tablet in half.

Though the fatigue and headaches were improved even on 15 mg a.m. and noon dosage, they were only mildly improved. However, on day 38 only taking ethinyl estradiol a mature follicle was attained. We suggested to retrieve the egg and fertilize it by ICSI because of the oligoashenozoospermia but not to transfer the embryo fresh, but freeze it because her symptoms of the increased cellular permeability syndrome were still present. There could be a higher risk of immune rejection of the fetus. Thus, one day 2 embryo with 4 blastomeres were cryopreserved for the future. No gonadotropins were given that cycle just human chorionic gonadotropin 10,000 IU at the time of follicular maturation with egg retrieval 32 hours later. Thus, an egg retrieval occurred in January 2016; the egg was frozen on day two because she had an anniversary party for her parents the next day so we cryopreserved a day earlier than intended so she could attend.

For about three months, her serum E2 remained less than 15pg/ml despite the continuance of ethinyl estradiol. However, the serum E2 began to rise, but the serum FSH remained over 20 mIU/nl so no gonadotropins were given. In May 2016, she had her second egg retrieval. The embryo reached 8 cells on day three. The frozen day 2 embryo had also been thawed and reached 12 blastomeres. Both embryos were transferred and she conceived and delivered a singleton healthy full-term baby. The amphetamine salts were continued throughout the entire pregnancy because as we tried to wean the dosage, the headaches and fatigue returned. They were completely eradicated with 60mg per day amphetamine salts.

She knew that the longer she waits between pregnancies, the less likely that there would be any eggs left. Thus, though she delivered the baby in February 2017, she wanted to try again in April 2017. She expected that it would take a much longer time to develop a dominant follicle, if at all. On the 24th day of ethinyl estradiol without any exogenous FSH stimulation, she attained a mature dominant follicle. The egg was retrieved, and she developed an 8-cell day 3 embryo. Given the option of cryopreservation and transfer at a later date or proceeding with a fresh transfer, she chose to transfer the 8-cell embryo fresh. Again, she conceived and delivered a full-term, healthy baby. Once again, she remained on dextroamphetamine for the entire pregnancy.

She delivered in January 2018. She continued on 60mg amphetamine salts and continued a relative headache free existence with good energy. We also gave her oral estradiol for treating her menopause, which in conjunction with the dextroamphetamine, prevented vasomotor symptoms [53,54]. She was given medroxyprogesterone acetate 10 mg x13 days every 3 months. She denied dysmenorrhea with the ensuing menses.

There is a long existing law in the state of New Jersey precluding the use of a drug with a class II narcotic prescription to be prescribed off-label. However, she had ADD which is an on-label use for ADD. For some reason, despite being very liberal with New Jersey residents able to acquire marijuana and medical psychogenic mushrooms without even seeing a physician, the Attorney General of New Jersey declared that it would be illegal for a New Jersey resident to acquire dextroamphetamine in another state if they do not have ADD even if it could ameliorate not only the aforementioned conditions mentioned in this manuscript

plus many others not mentioned. Many lawmakers consider this interpretation of the law as unconstitutional, but no one was willing to challenge the Attorney General. Furthermore, the Attorney General notified our group that even though the patient had ADD that we could no longer prescribe it because all doctors in the group were gynecologists, and that this drug in New Jersey could only be prescribed by neurologists, psychiatrists, and family physicians. The Attorney General was notified that the lead author is also board-certified in internal medicine. However, the attorney general insisted that there is a difference between internal medicine and family practice. Thus, we were precluded from prescribing it anymore. However, her family physician was willing to prescribe it, so she did continue the amphetamine salts until 2025 when her family physician retired. The physician who took over the practice refused to continue to prescribe it for her.

Though her cramps resumed, they only occurred 4x per year so she could bear with them. They were painful but not excruciating. She began noticing some episodes of shooting pain in her vagina which could last an hour then disappear. These transient vaginal attacks occurred in 2023. She thinks they occurred mostly when she could not obtain the amphetamine salts related to some drug shortages.

Now, with no dopaminergic drugs at all, the aforementioned vaginal pain, not only intensified, but was constant. Her description was that it felt like someone was cutting her vagina with knives. Nevertheless, intercourse did not make it worse, and thus she did not have dyspareunia.

When she came for her annual visit, she mentioned the vaginal pain, but there was no evidence of vaginitis and ultrasound was completely normal, and her pelvis was not tender on palpation. Vaginal cytology showed a good estrogen effect. She was prescribed cabergoline 0.5mg twice weekly but first started at 0.25mg for one week to get accustomed to the drug. She noticed that when she increased the dosage to 0.5mg twice weekly, the vaginal pain markedly improved by the end of that week. However, it would be present but much less intense, the day before the next dosage. Her pain has now been completely eradicated for six months taking cabergoline 0.5mg three times per week. She states that she has only mild headaches and mild dysmenorrhea. When asked to compare the effects of amphetamine salts compared to the cabergoline, she stated that the dextroamphetamine was superior to the cabergoline in improvement of fatigue, headaches, and dysmenorrhea. However, there is sufficient relief from the cabergoline that she will not try to find another New Jersey physician to prescribe amphetamine salts. Interestingly, the cabergoline seems to provide benefits for her ADD.

Discussion

Though the initial reason why we prescribed dextroamphetamine over 40 years ago was its effects on releasing dopamine, one could not be sure that the benefit was not from its release of catecholamines from sympathetic nerve fibers, or the combination with release of dopamine. Thus, severe burning pain of the vagina could be added to the growing list of conditions that we classify as part of the increased cellular permeability syndrome that also responds to cabergoline, including dysmenorrhea, headaches, and carpal tunnel syndrome [35,36,38].

Actually, in 1984 when we published our first case report on the beneficial effect of dextroamphetamine relieving severe treatment resistant, constant total body urticaria that had been present for 7 years in one case, within one week of taking dextroamphetamine and also relief of a second very severe case of urticaria, we had also considered the use of carbidopa levodopa [55]. However, there was more experience about the lack of teratogenic effects from using pharmacological dosages of dextroamphetamine and less knowledge of carbidopa levodopa because of the rarity of women with Parkinson's disease trying to conceive. We chose the former because not only would many of our patient population want to become pregnant while we are treating their various disorders, but we, as previously mentioned, thought it could also improve fecundity [42,43,56]. Actually, even today they have been only a few case reports of deliveries of babies from women taking carbidopa levodopa However, so far there have been no pregnancy outcome problems with carbidopa levodopa, except possibly one episode of a short course of seizures in a newborn, but still too few to be assured of safety during pregnancy [57-62].

Though there is some evidence that both dextroamphetamine and carbidopa levodopa may be more effective in treating the increased cellular permeability syndrome than cabergoline, there is more experience with the safety of cabergoline during pregnancy [37,63-66].

For reasons unknown, New Jersey is not the only place that makes it difficult to obtain amphetamines for treating various manifestations of the increased cellular permeability syndrome. A woman with primary infertility and dysmenorrhea, fibromyalgia and headaches was treated with dextroamphetamine sulfate, which completely eradicated these symptoms with the combination of the amphetamine and supplemental progesterone in the luteal phase. She conceived after two months and delivered a healthy baby [13-15,67]. Three months after delivery, her husband, who appeared extremely emaciated in the initial visit, and now was even worse, consulted us because he was writhing in pain, despite the oxycodone, OxyContin, and fentanyl combination for chronic pancreatitis. He was advised that death was imminent, probably in the next three months.

He was hoping that if he added the dextroamphetamine to his opiates, he may gain sufficient relief of the pain to enjoy his child for a short time. They lived in Pennsylvania, which has no law against the use of class II drugs off-label. At the eighth month of taking 90 mg amphetamine salts with no side effects, he advised us that he was now pain-free and also had gained 50 pounds. Even more impressive, he had completely stopped the opiates two months before. Because he lived an hour closer to his pain management physician, we asked if he might prefer to have that physician prescribe his amphetamine treatment. He advised us that he did in fact ask that question of the pain management physician who was

prescribing the opiate combination, and he told the patient that he "would not touch amphetamines with a 10-foot pole" [68].

Thus, despite the large number of reports of the high efficacy of dopaminergic agonists treatment of a large number of chronic conditions (many of which were resistant to standard therapy) by using dextroamphetamine sulfate there still seems to be a "black cloud" surrounding its use. Thus, there is a need to explore the use of other dopamine agonists, e.g., cabergoline, as in this case or carbidopa levodopa. Despite treating many women successfully gaining considerable relief for a variety of pelvic pain conditions over the last 50 years, we can only recall one other case of constant very severe vaginal burning pain, not attributed to infection or atrophic vaginitis, and that was in a child who not only quickly resolved the vaginal pain following treatment with dextroamphetamine, but also other manifestations of the increased cellular permeability syndrome [28].

Conclusion

Key Points

- It is possible to induce ovulation, in patients, who by all criteria are in menopause, by simply up-regulating down regulated FSH receptors by medications that suppress FSH followed by stimulation with endogenous or sometimes exogeneous LH and FSH.
- Inducing ovulation in menopausal women is not an exercise in futility because their eggs may have good quality and produce live babies. Merely using estrogen to lower serum FSH by inhibiting FSH release from the pituitary allowed the woman in the case report to make a mature follicle three times leading to the formation of three good quality embryos resulting in two live deliveries from just two embryo transfers.
- This patient was in her late 20s. Indeed, with POF and diminished egg reserve DOR similar to women with normal egg reserve, the younger, the woman, the better chance of a live delivery both with and without IVF-ET [69,70].
- There are menopausal women, however, who are in advanced reproductive age, who can achieve not only the development of a mature follicle by this FSH receptor of regulation technique, but live births even without exogenous gonadotropin stimulation [3,71].
- The most cost-effective method to lower serum FSH is to use compounded ethinyl, estradiol, not ethinyl estradiol, combined with a progestin as in an oral contraceptive. Though one may develop a mature follicle with the oral contraceptive, the progestin precludes a natural pregnancy because if it's effect on the endometrium.
- We have tried many different types of estrogens available on the pharmaceutical market other than ethinyl estradiol, but we found ethinyl estradiol to be the best option because it effectively suppresses FSH release from the pituitary. However, most importantly, it does not contribute at all to the serum estradiol level, allowing monitoring of follicular maturation by the serum E2 levels. The technique sometimes does require a small boost of gonadotropins or GNRHant as described in the introduction both for natural cycles and IVF cycles. Some examples of this technique with day-by-day decision have been recently published in for IVF cycles with extremely low AMH levels [72].
- Ovulation induction and successful pregnancies are not that uncommon despite DOR. We published a lot of case reports in the 1980s and 90s illustrating different examples, but in the last two decades we have only written case reports when there was some subject, we wanted to bring to the attention to other clinicians, researchers, or students. We did summarize cases of POF conceiving with IVF-ET in 2016, but this case conceiving in 2017 and 2018 was obviously not included [73]. Even the case of the 46.5-year-old woman who in apparent total menopause who similarly conceived only with ethinyl estradiol, progesterone, and natural intercourse was not published until eight years after she delivered [3]. We wrote the case of the 46.5-year-old woman to discuss the luteinized unruptured follicle syndrome and a new method to release eggs from the follicle even when all other options failed, i.e. the use of granulose colony stimulating factor [74]. She was also treated with dextroamphetamine sulfate.
- The cause of POF or DOR in the absence of ovarian surgery, chemotherapy, or radiation therapy is likely to be autoimmune damage to the oocytes.
- Evidence suggests that there is a necessity to create an autoimmune state related to an increase in NK cells, macrophages, and cytotoxic t cells during the luteal phase to create thin-walled spiral arteries from thick wall, and uterine arteries to enable nutrient exchange between mother and fetus.
- Evidence suggests that excessive cellular permeability is the cause of an excessive inflammatory response leading to egg depletion. However, it can contribute to immune rejection of the fetus when women with POF or DOR are made to ovulate.
- Taking dopamine agonists can decrease excessive permeability, thus reducing excessive inflammation. We have had the most success with the dopaminergic agonist sympathomimetic dextroamphetamine for treating pelvic pain or other medical conditions related to increased cellular permeability. We have also had good success with other dopamine agonists e.g., cabergoline or carbidopa levodopa. Treating these conditions also helps fecundity preventing immune rejection of the fetal semi-allograft.
- The stimulation for writing this case report was not just to write another success of reversing menopause and achieving a successful pregnancy, but more to demonstrate another case of dopaminergic drugs to relieve a type of pelvic pain. Only this time showing that both cabergoline and dextroamphetamine sulfate were effective. Interestingly, this is only the second time we have treated a case of severe constant vaginal pain not associated with dyspareunia, and as mentioned, the first case

was in a six-year-old child using dextroamphetamine, and this case of a woman in her 30s used cabergoline [28].

- This case report shows that the dosage of cabergoline that was needed to treat the increased cellular permeability syndrome is much higher than the dosage needed to treat galactorrhea or hyperprolactinemia or even prolactinomas.

- Overall, one of the main objectives is to familiarize fellow clinicians, and students with the increased cellular permeability syndrome, and its many clinical manifestations.

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