

Case Report

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The Dopamine Agonist Dextroamphetamine Sulfate as A Highly Effective Therapy for Dystrophic Epidermolysis Bullosa

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Abstract

Dystrophic epidermolysis bullosa (DEB) is a monogenic inherited skin fragility disorder that presents with painful skin blisters usually from early childhood. There is no effective standard therapy for DEB at present, just mostly hygienic care to prevent infection. Dopamine agonists, e.g., dextroamphetamine or lisdexamfetamine have been successful in treating other treatment refractory skin disorder e.g., bullous pemphigoid, chronic urticaria, long term eczema, palmoplantar eczema, and discoid lupus erythematosus. The hypothesized mechanism is that dopamine diminishes cellular permeability thus inhibiting infiltration across mucosal barriers of irritating substances leading to the inflammatory response. A 35-year-old woman was treated with 60mg of lisdexamfetamine and the lesions dissipated after one week and the continued use has prolonged the remission to 2.5 years. This is the first case reporting successful dopamine agonists therapy for DEB.

Keywords: dystrophic epidermolysis bullosa; increased cellular permeability syndrome; dopamine agonists; inherited monogenic disorders

Introduction

There are a group of skin fragility disorders related to mutations in the gene responsible for encoding the alpha-1 chain type of VII collagen (C7) which is a fundamental component of the anchoring fibrils within the dermis-epidermis junction of the skin and also the mucus membranes [1]. The mutation is in the gene COL7A1[1]. The skin fragility resulting from the disruption of adhesion of epidermis to dermis makes the skin more susceptible to tearing even with only mild mechanical stress.

There are various presentations from relatively mild to severe depending on which of the 16 different genes are the etiologic factor for this skin fragility disorder which is collectively known as dystrophic epidermolysis bullosa (DEB) [1,2].

The skin lesions may vary from blisters, or ulcers, or skin peeling or erosions [3]. Actually, the 16 different mutations are responsible for four different types of epidermis bullosa anchoring disorders: 1-compromising EB simplex (separation of the basal dermis) 2- junctional EB (separation within the lamina lucida) 3-kindler EB (separation at multiple planes) and 4 dystrophic (DEB) (separation of the upper dermis below the lamina densa [1]). Actually, it is the DEB type that is related to various mutations in the COL7A1 gene. The conditions may be caused by a mutation in a dominant gene which tends to lead to

milder skin disorders than the types related to homozygosity [2]. More often dominant DEB presents with milder phenotypes e.g., localized skin blistering often with dystrophic fingers and toenails related to the generalized increased pressure on these body parts [1,2]. The dominant form is usually associated with a normal lifespan, but it may be shortened with the recessive form [1,2].

According to Salt et al “Currently there is no definitive treatment, and cure remains elusive for epidermolysis bullosa” [3]. This treatment may involve wound care, e.g., regular dressing changes, and use of protective bandages, and the judicious use of antibiotics to treat and prevent infection. Frequently these patients are treated with non-steroidal anti-inflammatory drugs and anti-pruritic drugs e.g., antihistamines for pain and pruritus.

Presented here is a case report responding to a novel treatment for DEB but not a novel treatment for other blistering types of skin disorders, and that is the use of a dopamine agonist lisdexamfetamine similar to DS [4-6].

Case Report

35-year-old women consulted our group for primary infertility present for 3.5 years. She came from a city that was 800 miles away. She consulted us to get a second opinion. The opinion from her first

reproductive endocrine infertility (REI) consultant was that because she has diminished oocyte reserve (DOR), as evidenced by a serum anti-mullerian (AMH) level of 0.8ng/ml (low egg reserve considered if serum AMH <1ng/ml), the REI advised her that her prognosis for achieving a live delivery with her own eggs was unlikely. Furthermore, because of her condition of the dominant form of DEB that she was advised that she should just obtain eggs from a donor especially since because of a severe problem of oligoasthenozoospermia (OA), in vitro fertilization embryo transfer (IVF-ET) with intracytoplasmic sperm injection (ICSI) would be needed anyway, and using donor eggs would obviate the risk of DEB in child. A second REI who she consulted was willing to do IVF with her own eggs and ICSI, and also do pre-implantation testing for monogenic disorders (PGT-m) and PGT for aneuploidy (PGT-a) to not only avoid the 50% chance of DEB in her child but also inhibits her “increased risk for a fetus with aneuploidy” (in her opinion).

Interestingly, this woman had a history of blisters described as being very irritated and raw resulting in more pain than pruritus which would last about 1 week, then heal with peeling during the next week, only to reoccur one week later. The blisters would occur predominately on the hands, elbows, feet, and knees and were present since at least the age of 3. Both the fingernails and toenails were dystrophic. Though this clinical presentation is characteristic of DEB, probably related to its rarity, the diagnosis was not made until age 34 when her first REI ordered a comprehensive monogenic carrier screening test which is typically ordered by most REI physicians especially in cases where IVF-ET is considered. Fortunately, the patient never progressed to any serious infection from her DEB. She was advised by her pediatrician and her family physician that she just had sensitive skin.

The second consulting REI wanted to use a controlled ovarian hyperstimulation regimen with a high dosage of follicle stimulating hormone (FSH) which would significantly increase the cost of the IVF-ET, plus the additional expense of PGT-a and PGT-m and embryo freezing that would be required. This influenced her to check social media, and she became aware of our REI practice that is highly experienced with patients with DOR. We advised her that our data supports the concept that high dosage FSH down regulates FSH receptors needed to produce enzymes or cytokines needed for embryo implantation [7]. We strongly

recommended that if they chose to proceed with IVF-ET with their own eggs to use a type of COH which requires using much lower dosages of FSH stimulation which is known as an FSH receptor up regulation technique [8]. She was also advised that if she wanted to save the most money, she could try to achieve a pregnancy without IVF-ET following similar tenets of avoiding down regulation of FSH receptors from causing too high of a serum FSH level by high dosage FSH stimulation. Even this technique could require expensive gonadotropin stimulation drugs and gonadotropin releasing hormone antagonists, but the dosage would be even lower than used for IVF-ET [9]. Her husband had moderately severe OA, but we thought that this was likely to using exogenous testosterone. Thus, we advised them if they wanted to conceive right away IVF with ICSI would be needed. However, if they were willing to wait several months, we suggested that there was a good chance the sperm quality would return to normal and natural conception would be possible. They decided since there was no guarantee that the sperm would become normal, they decided to proceed with IVF-ET because her egg depletion may continue.

We also advised her that the risk of a trisomy in the fetus based on our own studies does not suggest that DOR in young women increased their risk of trisomy 21,13, or 18 i.e., the ones that can lead to a live delivery [10]. Thus, we disagreed with her two previous consultants. However, the question of PGT-m for DEB could still be a reason to consider IVF over natural conception. Though fortunately she has the mild form of DEB i.e., with a dominant gene mutation, as opposed to being homozygous for the recessive gene, and she has lived with her frequent blisters, and to date, was fortunate not having them develop into more serious infections, the possibility was that her child may not be as fortunate.

She was advised by our group that we have successfully treated various dermatologic conditions with dopamine agonists, and the one most commonly used was dextroamphetamine sulfate (DS) [11-14]. We explained that the evidence supports the concept that the creation of spiral arteries during the luteal phase and during the actual pregnancy needed for nutrient exchange between mother and fetus develops more from autoimmune remodeling of thick-walled uterine arteries predominately found during the follicular phase [15]. Evidence supports the concept that the infiltration of cellular immune cells needed to strip off the thick cellular walls is strongly influenced by

irritating elements traversing the mucosal barrier [15]. The infiltration seems to be enhanced by the early secretion of progesterone (P) by the corpus luteum [15]. The P is hypothesized to inhibit the effect of dopamine in diminishing cellular permeability and thus preventing irritants from traversing the mucosal barrier [15].

However, the cellular immune cells found in the fetal placental microenvironment (70% natural killer cells, 20% macrophages, and 10% cytotoxic T-cells) need to be neutralized by P by activating membrane P receptors on rapidly growing cells (embryonic cells, mesenchymal cells, and trophoblast cells) to create immunomodulatory proteins (e.g., the progesterone induced blocking factor (PIBF)) that help to negate the killing activity of these cellular immune cells [15,16].

Sometimes if there is relatively too much cellular immune activity merely supplementing extra P from early luteal phase is sufficient to negate the excessive killing activity preventing immune rejection of the early conception leading to infertility or somewhat later in pregnancy leading to miscarriage [17,18]. However, sometimes with excessive infiltration of irritants into pelvic tissues there is too much cellular immune activity to negate even with supplement P. Thus, it may be necessary to suppress excessive infiltration of irritants by treating with dopaminergic drugs to decrease cellular immunity by inhibiting irritants traversing the mucosal barrier [15,16].

The patient had a history of dysmenorrhea that was not relieved by non-steroidal anti-inflammatory drugs. We explained to her that this pain is more often associated with an excessive inflammatory cellular immune presence which could possibly lead to immune rejection of the fetus. In fact, women with a history of dysmenorrhea with or without the documented presence of endometriosis related to an increase in pelvic tissue inflammation may be the actual cause of the DOR with immune attack of the ovaries [15, 16, 19,20]. Thus, the treatment with dopamine agonists may not only benefit her by helping her to decide as to whether to do PGT-m or not for DEB, and relieve her of recurrent blisters, but may help her to have a successful pregnancy outcome whether she chose to try to conceive naturally or with IVF-ET [15,21]. Another benefit of treating with dopamine agonists is by potentially improving her quality of life by reducing the frequency and intensity of her skin blisters related to her DEB, also it could slow down the rate of egg depletion [22].

The couple lived in Tennessee, 800 miles from our New Jersey or Pennsylvania facility. Dextroamphetamine sulfate or lisdexamfetamine are class II drugs and require the monthly prescription to be obtained by a pharmacy in the state where the prescribing physician has a license. Her family physician in Tennessee was willing to prescribe 60mg lisdexamfetamine capsules daily.

As mentioned, her husband had OA possibly related to his use of exogenous testosterone injections. He was started on 25mg/day clomiphene citrate and 2000IU injections of human chorionic gonadotropins three times per week in case the IVF-ET was unsuccessful. If failure to conceive after the first IVF-ET, and if the sperm subsequently improved sufficiently, they could try to conceive naturally to save the expense of IVF-ET.

The lisdexamfetamine was started during a week when there were no active lesions, just the peeling. The blisters did occur the next week but were milder in intensity. However, she had no more lesions for the next six weeks. Thus, satisfied that there be an effective treatment even if her child inherited the dominant gene for DEB, coupled with the long distance, and complicated by a male factor problem, the couple's final decision was to proceed with ICSI if the sperm count was still too low to risk conventional oocyte insemination.

Using the FSH receptor up-regulation form of mild controlled ovarian hyperstimulation, but because of the treatment of the male partner resulted in a normal semen analysis, conventional oocyte insemination was used.

Three oocytes were retrieved and all three fertilized. One embryo arrested before three days after fertilization, but two embryos (a 7-cell and 8-cell) were transferred on day 3. A single pregnancy ensued with the delivery of a full-term healthy baby by cesarian section. Her serum AMH was 0.61 at the start of the cycle. The lisdexamfetamine was continued throughout the entire pregnancy and there were no episodes of blisters during that time. Post partum, she would get occasional feet and hand blisters lasting only 3-4 days with much less pain for 2.8 years while remaining on lisdexamfetamine even during nursing. Two other medical conditions associated more with the increased cellular permeability syndrome, but not necessarily associated with DEB, i.e., premenstrual headaches and upper right quadrant abdominal pain which, was present since childhood, also markedly improved with lisdexamfetamine [23-31].

Probably even the mild presence of DEB symptoms, the premenstrual headaches, and the abdominal pain, could have been further improved if the dosage of lisdexamfetamine was increased, but the physician in Tennessee was reluctant to raise the dosage further. The couple returned to help her achieve another pregnancy. Her husband was no longer taking exogenous testosterone and they had a normal post-coital test. Thus, IVF was no longer needed. Since she made a mature dominant follicle, we treated her with luteal phase supplemental progesterone (P). She conceived in just one cycle of P vaginal suppositories and so far, her pregnancy is doing well during the first trimesters. As before, she will continue the lisdexamfetamine through the entire pregnancy.

Discussion

Alexander Nystrom is considered one of the world's leading experts on DEB and has provided a very good up to date summary of this condition entitled, "DEB-from biochemistry to interventions" [35]. Obviously, one successful case report with treating the dominant form of DEB informs the reader that this dopamine agonist therapy can be effective, but one may question whether it is only effective in a minority of cases or a majority? Another question is whether it will only treat the form of DEB related to a dominant gene mutation or would it also effectively improve the condition in the more serious homozygous recessive type?

However, DEB is a rare disorder and is estimated to be present in about 1 in 80,000 people [36-38]. Thus, it would be quite difficult to evaluate its efficacy in a large series. Hopefully, this case report will generate interest in some of the experts who may be referred a larger group of patients with DEB to help answer these questions.

It is clear related to her long history from early childhood of DEB, and with the marked improvement with lisdexafetamine that this drug is responsible for the improvement in her skin condition. It is suspected, but not proven, that the use of dopamine drugs helped her to have a successful pregnancy similar to other patients treated with dopamine agonists for infertility. This treatment may help to eradicate, or at least markedly improve other autoimmune conditions that were refractory to standard therapy e.g., Crohn's disease or ulcerative colitis while at the same time improve fecundity by preventing cellular immune rejection of the fetus [39,40]. Thus, it is common for patients to remain on

the dopamine agonists even after the delivery and in women who no longer want any more children [16,41]. The increased cellular permeability syndrome resulting in a plethora of chronic disorders that are frequently refractory to standard therapy and are more effectively treated by dopamine agonists, are not restricted to females. Headaches and some cases of severe life-threatening cases of treatment refractory abdominal pain e.g., from mesenteric sclerosis and chronic pancreatitis in males responded very quickly and effectively following treatment with amphetamines similar to the case reported (though her headaches and abdominal pain were not nearly as severe as the cases reported for males with this condition [42,43]. Other conditions that were effectively treated by the dopamine agonist dextroamphetamine in males included severe long-term post-herpetic neuralgia, dysorgasmia, chronic sinusitis, and polymyalgia rheumatic [44-47].

Other dopamine agonists e.g., cabergoline, and carbidopa levodopa have successfully treated cases with conditions related to increased cellular permeability e.g., pelvic pain and dysmenorrhea, headaches, carpal tunnel syndrome, and chronic regional pain syndrome [48-51]. Our experience is drugs that release dopamine from sympathetic nerve endings are more effective than dopaminergic drugs that inhibit dopamine re-uptake.

Declarations

Conflict of Interest

None

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