Topical/Vaginal Treatment of Sexual Function Disorders

SUMMARY: Two female patients were diagnosed primarily with low libido and were prescribed sildenafil 2% combined with arginine hydrochloride (HCl) in PCCA Ellage® Anhydrous Vaginal (PCCA Formula 14338), to be applied once a day for approximately 3 months. Both patients were satisfied with the treatment outcome and reported no adverse events. The biggest improvements attributed to the compounded topical/vaginal treatment were in the desire and arousal sexual domains, followed by the satisfaction, lubrication and pain domains.

Submitted by: Masoud Rashidi, RPh, and Anna Rashidi, RPh, Innovative Compounding Pharmacy, Folsom, CA, USA.

Introduction:

It is estimated that sexual function disorders affect about 43% of women, impacting significantly on their interpersonal functioning and overall quality of life[1]. Over recent years, there has been an increase in the clinical and academic interest in Female Sexual Dysfunction (FSD), which is commonly divided into four key domains: sexual pain, low desire, low arousal, and orgasmic dysfunction. Sexual pain is a common complaint in women of all ages and may include pain at the vulva, deep pain with penetration, or tightening of the pelvic musculature. Women with low desire will experience an absence or reduction in sexual fantasies and desire for sexual activity that causes distress. Sexual desire is fluid throughout a lifetime; however, at various points in one's life, low sexual desire may cause significant distress. Low arousal may manifest as a decrease in vaginal lubrication and a decrease in genital warmth related to blood flow. Orgasmic dysfunction requires distinguishing between completely absent orgasms and delayed or less intense orgasms[2]. The purpose of this case series is to discuss the clinical efficacy of a compounded topical/vaginal treatment of two women diagnosed with FSD.

Case Reports:

Two female patients, aged 49 and 58 years old, were diagnosed primarily with low libido and were prescribed sildenafil 2% combined with arginine hydrochloride (HCl) in PCCA Ellage® Anhydrous Vaginal (Figure 1). In both cases, the compounded topical/vaginal treatment was applied once a day, in the evening, over a period of approximately 3 months. The corresponding PCCA Formula 14338 is displayed in Table 1.

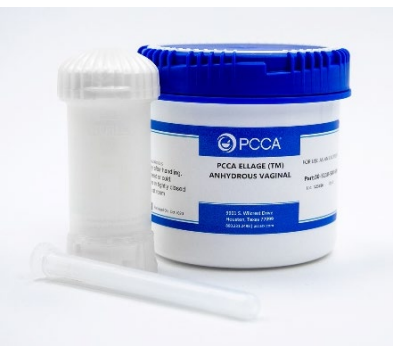

Figure 1. *PCCA Ellage® Anhydrous Vaginal.*

Rx	
Sildenafil Citrate USP	2.8 g
Arginine HCl USP	5 g
Glycerin USP (Natural)	5 g
Base, PCCA Ellage® Anhydrous Vaginal	87.2 g

Table 1. *Sildenafil 2%, Arginine HCl Topical/Vaginal (Ellage® Anhydrous).*

Sildenafil citrate is a type-5 phosphodiesterase (PDE_5) inhibitor which is commonly indicated in low libido and may be prescribed either alone or combined with arginine HCl[2-4]. Ellage is a mucoadhesive, anhydrous and self-emulsifying vaginal base, which is expected to adhere to the vaginal mucosa for a long period of time, despite the variable secretions of vaginal fluid, due to its high retention potential demonstrated *in vitro*[5,6].

Methodology:

The Female Sexual Function Index (FSFI) was the research instrument used in this case series to evaluate the clinical efficacy of the compounded topical/vaginal treatment. This multidimensional, self-reported instrument is comprised of 19 items which evaluate six domains of the female sexual function (desire, subjective arousal, lubrication, orgasm, satisfaction, and pain). Individual domain scores and a full scale (overall) score are derived from the computational formulas by Rosen *et al.* (2000). Scores are rated from 0-5; a domain score of zero indicates that the subject reported having no sexual activity[7].

The patients were requested to complete the FSFI before and after the compounded topical/vaginal treatment. Informed consent was provided by both patients.

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Results and Discussion:

The two female patients were satisfied with the treatment outcome and reported no adverse events. The FSFI was completed before treatment and approximately 3 months after treatment. When compared to baseline, there was an improvement in almost all domains of the female sexual function (desire, subjective arousal, lubrication, orgasm, satisfaction, and pain). Orgasm was the only domain which remained unchanged throughout treatment but this a complex domain that requires a multidimensional approach to treatment.

The biggest improvements attributed to the compounded topical/vaginal treatment were in the desire and arousal domains. Satisfaction improved equally but moderately in both patients; this is also a complex domain, less tangible than all other domains of the female sexual function. Lubrification, on the other hand, showed higher improvements in one patient but both reported increased lubrification. With regards to the pain domain, there was a remarkable improvement in one patient who suffered from deep pain with penetration. The patient commented the following:

"I need more (compounded topical/vaginal treatment) because it really did help with the pain."

The other patient did not suffer from pain and thus the scores remained unchanged.

The overall improvements in the female sexual function of both patients following the treatment with Sildenafil 2%, Arginine HCl Topical/Vaginal (Ellage Anhydrous) suggest that this compounded medication is a promising treatment option for female patients with sexual function disorders, in particular low libido. The vaginal route of administration was chosen because the vaginal mucosa offers a large surface area with a rich blood supply, making it an ideal site for the delivery of medication. Also, it is well documented that sildenafil citrate and arginine HCl are effective in enhancing sexual desire and arousal[2-4]. When incorporated in PCCA Ellage Anhydrous Vaginal, the contact time between the active pharmaceutical ingredients and the vaginal mucosa is likely to be extended because of the mucoadhesive properties of the compounding base[5,6]. Therefore, Ellage was the compounding base chosen to effectively deliver sildenafil citrate and arginine HCl.

Figure 2. *Representation of sexual function disorders (adapted from VGstockstudio/Shutterstock.com).*

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