Results: Of the 1261 vulvoscopic photographs, 767 (61%) were determined adequate for assessment and 614 photographs represented individual patients. The study group with clitoral adhesions consisted of 140 (23%) women of which 44%, 34%, and 22% demonstrated mild, moderate and severe clitoral adhesions, respectively. In the study group, 14% presented with clitorodynia. Risk factors included a history of sexual pain, yeast infection, urinary tract infection, blunt perineal/genital trauma, lichen sclerosus, low calculated free testosterone and other sexual dysfunction including persistent genital arousal disorder (PGAD).
Conclusion: Women with sexual dysfunction should routinely undergo clitoral physical examination. Should the glans corona not be fully visualized, clitoral adhesions should be suspected. Education, counseling and/or referral to sexual medicine specialists should be considered.
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EXTENT OF FEMALE PARTNER SEXUAL FUNCTION IMPROVEMENT IN FEMALE PARTNERS OF MEN WITH PEYRONIE'S DISEASE WHO RECEIVED COLLAGENASE CLOSTRIDIUM HISTOLYTICUM

Goldstein, I.[1]*; Liu, G.*[2]*; McLane, M.*[2]*; Hurley, D.*[2]
[1]*Alvarado Hospital, USA;* [2]*Endo Pharmaceuticals Inc., USA*

Objective: To examine the impact of erectile dysfunction severity in men with Peyronie's disease (PD) on improvement of female partner satisfaction after collagenase clostridium histolyticum (CCH) treatment.
Material and Methods: Men with PD (penile curvature $\geq 30°$ and $\leq 90°$) who previously received placebo during the IMPRESS I or II trials and their female partners, who were willing to participate, were included in a separate subsequent open-label, phase 3 study. Men received up to 4 treatment cycles; cycles were separated by 6 weeks. Each treatment cycle consisted of 2 injections of CCH 0.58 mg separated by 24 to 72 hours. The second injection was followed by 6 weeks of daily penile plaque modeling. Men completed the International Index of Erectile Function (IIEF) at baseline and week 36. The IIEF is a 15-item questionnaire that assesses 5 domains (erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction) of male sexual function. Female sexual function was assessed at baseline and week 36 using the Female Sexual Function Index (FSFI), a 19-item questionnaire that measures desire or arousal, lubrication, orgasm, satisfaction, and pain. The relationship between baseline IIEF male erectile dysfunction and improvement of female sexual function after CCH therapy in males was examined using regression analysis (Pearson correlation coefficient [r]).
Results: Thirty female partners, of men with PD who received at least 1 CCH injection during the study (N=189), volunteered to participate. Of these, 24 completed the FSFI questionnaire at baseline and week 36. Baseline IIEF erectile function subscale (IIEF-EF) score negatively correlated with changes from baseline in overall FSFI total score (r = -0.75; P<0.001) and most FSFI subscale scores: sexual arousal (r = -0.67), lubrication (r = -0.64), orgasm (r = -0.68), satisfaction (r = -0.62), and pain (r = -0.72); $P \leq 0.001$ for all). The regression coefficient of baseline IIEF-EF score and FSFI full scale score was -0.74 (P<0.001), suggesting that for every 1-point increase in baseline IIEF-EF severity, CCH provided an approximately 1-point improvement in female partner sexual function.
Conclusions: Improvement in sexual function of female partners negatively correlated with the baseline severity of erectile function in males with PD who were treated with CCH. This illustrates the impact of PD on female partners and the value of PD treatment in male partners.
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BP101 NEW MOLECULE FOR HSDD TREATMENT - RESULTS OF PROOF-OF-CONCEPT PHASE 2A STUDY

Nemenov, D.; Lomonosov, M.; Golikov, D.
IVIX Ltd., Russia

Objectives: BP101 is a peptide drug candidate aiming to restore sexual desire and related functions in women suffering from Hypoactive Sexual Desire Disorder (HSDD) and related sexual dysfunctions. In the Phase IIa clinical study BP101 efficacy and safety was assessed in premenopausal women with female sexual dysfunctions equivalent to HSDD.
Materials and Methods: This was a randomized, placebo-controlled trial in which 110 adult premenopausal women were enrolled. After 4-weeks screening period all patients were randomized in 1:1 ratio to 4-week intranasal treatment by BP101 or placebo with subsequent 8-week follow-up. End points included changes after 4 weeks of the therapy and after 4 and 8 weeks of follow-up compared with the baseline in Female Sexual Function Index (FSFI) total and desire domain scores.
Results: Compared to placebo, BP101 demonstrated increase in mean (SD) FSFI total score 5.97 (5.383) vs 3.93 (5.594) (treatment difference p=0.0522) at the end of treatment, 6.77 (5.597) vs 4.05 (6.085) (treatment difference p=0.0117) at the follow-up week 4, and 6.23 (6.072) vs 4.05 (5.801) (treatment difference p=0.0533) at the follow-up week 8; also in mean (SD) FSFI desire domain score 0.95 (0.950) vs 0.67 (0.899) (treatment difference p=0.0852) at the end of treatment, 1.15 (1.103) vs 0.65 (0.995) (treatment difference p=0.0076) at the follow-up week 4, and 1.04 (0.990) vs 0.68 (0.902) (treatment difference p=0.0290) at the follow-up week 8. The most frequently reported adverse events in the BP101 group were headache, nasal dryness, irritability, glycosuria and proteinuria, which were not likely or possible related to study drug and were mild or moderate in severity. All cases of glycosuria and proteinuria were reported at the same time in the same center, and were not confirmed by corresponding laboratory retesting.

Conclusions: BP101 showed promising efficacy and favorable safety profile in this proof-of-concept clinical study. Valuable data was collected for planning upcoming pivotal BP101 clinical studies in HSDD patients.
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USE OF AUTOLOGOUS DERMAL TISSUE PRESERVES SEXUAL FUNCTION AFTER PELVIC ORGAN PROLAPSE SURGERY

Nagao, K.; Okawa, M.; Iwai, H.; Tai, T.; Tanaka, N.; Kobayashi, H.; Nakajima, K.
Toho University, Japan

Objective: Established surgical methods for pelvic organ prolapse include use of tension-free vaginal mesh and laparoscopic sacrocopopexy. However, an alert by the US Food and Drug Administration has increased patient anxiety about foreign body insertion. We developed a method of autologous dermal tissue transplantation for treatment of pelvic organ prolapse. This technique improves operative safety and effectiveness and preserves sexual function. Because blood flow is supplied from the uterine and mucosal sides of the bladder, and the engraftment rate is high. To evaluate the safety and effectiveness of using autologous dermal tissue for surgical repair of pelvic organ prolapse.
Methods: The procedure was performed by adding dermal transplantation to cystocele/uterine prolapse surgery, which does not use conventional mesh, under general anesthesia. First, we resected the epidermis of abdominal skin and defatted the dermis. Next, the mucosa of the vaginal posterior wall was longitudinally dissected, and 2-0 TiCron (nonabsorbable suture) was applied to the left and right sacrospinous ligament (two stitches a side; four stitches in total). A vertical incision was made in the anterior vaginal wall, and 2-0 TiCron was stitched to each side of the arcus tendineus fascia pelvis (two stitches in total). The bladder was sutured with a 3-0 Vicryl three-needle horizontal mattress suture. The dermis was implanted on the bladder and anterior wall of the cervix and was placed on the sacrospinous ligament and the arcus tendineus fascia pelvis. The posterior wall of the uterine cervix was lifted to the sacrospinous ligament. The patient was discharged on the fifth day after surgery and used an external pessary (FemiCushion) for 2 months postoperatively, until the graft was firmly engrafted. This external pessary supports the pelvic floor muscle and can be used before surgery after removing a vaginal pessary, thereby improving patient quality of life. Patients can also use the external pessary if they develop sexual dysfunction while using a vaginal pessary.
Results: No urinary complications or recurrence were observed. Scarring was minimal at the site of dermal collection, and patient satisfaction was high.
Conclusions: Our results suggest that use of autologous dermal tissue is safe, effective, and efficient for treatment of pelvic organ prolapse. The outcomes for this operation are comparable to those for procedures using fascia, and the present procedure does not affect patient sexual function.
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THE PLACEBO EFFECT FOR A RADIOFREQUENCY MEDICAL DEVICE TREATING VAGINAL LAXITY

Krychman, M.[1]; Tapscott, A.[2]
[1]Southern California Center for Sexual Health and Survivorship Medicine Inc, USA; [2]Sexual Health Institute of the Carolinas, Carolina Urology Partners, Huntersville, NC

Objective(s): To determine the placebo effect for a medical device that uses monopolar radiofrequency with cooling when treating women who are complaining of distressing impactful vaginal laxity/looseness.
Material and Method(s): A prospective, longitudinal, randomized, blinded, placebo-controlled, multi-center clinical study was carried out for the treatment of impactful vaginal introital laxity that affected sexual satisfaction. The treatment is an outpatient monopolar radiofrequency procedure that couples heating underlying tissue while cooling and protecting the vaginal mucosa. Efficacy and safety have been published elsewhere. This international study is the first and only of its kind ever done for the medical treatment for the condition of vaginal laxity. Subjects were randomized in a 2:1 ratio to either the active (90 J/cm^2) or sham ($\leq$1 J/cm^2) treatment groups. Nine sites were chosen in multiple countries (Italy, Spain, Canada and Japan). Subjects were followed up at 72 hrs., 10 days, and 1, 2, 3, and 6 months post-treatment. Patient reported outcomes included a 7-point Likert scale assessment for vaginal laxity and the Female Sexual Function Index (FSFI).
Result(s): A total of 155 premenopausal female subjects that did not have any major protocol deviations were included in this analysis. The procedure was well tolerated, preformed on average in 30 minutes in an outpatient setting without the need for topical anesthesia or pain medications. Recovery to activities of daily living including sexual intercourse was immediate. Results demonstrated a statistically significant, clinically meaningful difference at 6 months between active treatment and sham intervention. The active treatment group 3 times more likely to report "no laxity" ($p \leq 0.006$). However, the sham treatment group showed a substantial treatment effect itself, with a 31%, 33%, and 19% increase in "no laxity" at months 1, 3, and 6, respectively.
Conclusion(s): In order to adequately power and design future research initiatives, investigators must take into account the possibility of a substantial "sham effect" for laxity and vaginal function studies; underscoring the importance of placebo/sham-controlled trials to ensure that the effect being seen is actually due to the investigational product.
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