Compounding Options in Women’s Health

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Why Compounding Options are Important in Women’s Health

- Medication on backorder or unavailable
- Side effects of therapy; compliance
- Treatment failure with current therapy
- Combination customized prescription can target the problem with multiple mechanisms of action
Why Compounding Options are Important in Women’s Health

• Skyrocketing commercial drug prices
  – Insurance rejections with many commercial drugs
  – Unaffordable copays

• Compounds offer a variety of clinical options with unique innovative bases and dosage forms
Bases Used in Women’s Health

• VersaBase® Cream
• VersaBase® Gel
• Lipoderm®
• Estradiol 10mg/gm dilution
• Estriol 10mg/gm dilution
• MucoLox™
PCCA’s VersaBase® Cream is an elegant, yet extremely durable, cosmetic cream. It simulates the natural moisturizing barrier of the skin through its emulsion system, can be used for a variety of pharmaceutical and cosmetic applications, and is great for topical hormone replacement therapy.
VersaBase® Cream

• When comparing the bases abilities to transport progesterone deep into the dermis, VersaBase® Cream out-performed all bases and delivered more than 4 times as much progesterone as the commercial base Vanicream®.

• PCCA Document #97711 – VersaBase® Cream, gel, Cosmetic HRT/Progesterone Study Results
• VersaBase® Gel is a versatile topical gel base that demonstrates excellent resiliency to low pH (2-7.5) and good compatibility with polar solvents, while maintaining a pleasant, silky feel. This gel can be used vaginally and on mucous membranes.
Lipoderm®

- This elegant alternative to traditional PLO gels contains a proprietary liposomal component that may increase the permeation of a variety of actives. Lipoderm® can be used in place of PLO gels for transdermal compounding. Its touch and feel is smooth and creamy, unlike the tacky feel of PLOs.
Estradiol 10mg/Gm Dilution & Estriol 10mg/Gm Dilution

• Naturally derived solvent system
  – Heptyl Glucoside, Olive Oil Glycereth-8 Ester
  – Patent Pending
  – Patch Tested (RIPT)

• Convenience and safety
  – No weighing of static prone powders, Easy to withdraw and add to cream
  – Reduced exposure risk, due to no powder dust

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Estradiol 10mg/Gm Dilution & Estriol 10mg/Gm Dilution

• **Ease of use and improved mixing**
  – Better resulting content uniformity (hormones are already in solution)

• **Improved efficiency**
  – Liquids easier in the mixing/compounding process
  – Lower mixing times (see formulas)
  – No milling necessary
Estradiol 10mg/Gm Dilution & Estriol 10mg/Gm Dilution

• Improved permeation characteristics
  – *In Vitro* Permeation of Estradiol Using a 3D Model of Human Epidermis
  – Findings show that PCCA Estradiol dilution (in patent pending solvent system) shows increased in-vitro permeation of estradiol through the epidermis compared to estradiol dissolved in propylene glycol and ethoxy diglycol.
Estradiol 10mg/Gm Dilution & Estriol 10mg/Gm Dilution

- **Formulation examples (topical and vaginal preps only)**
  - PCCA Formula #12017 - Estriol/Estradiol [50%/50%] 0.5 mg/0.5 Gm Topical Cream
  - PCCA Formula #12019 - Estriol/Estradiol [50%/50%] 0.5 mg / Progesterone 25 mg/0.5 Gm Topical Cream
  - PCCA Formula #12021 - Estriol/Estradiol [80%/20%] 0.625 mg/0.5 Gm Topical Cream
  - PCCA Formula #12022 - Estriol/Estradiol [80%/20%] 0.625 mg / Progesterone 25 mg/0.5 Gm Topical Cream
Estradiol 10mg/Gm Dilution & Estriol 10mg/Gm Dilution

• Formulation examples (topical and vaginal preps only)
  – PCCA Formula #12029 - Estriol/Estradiol [80%/20%] 1.25 mg/Gm Topical Gel (VersaBase®)
  – PCCA Formula #12030 - Estradiol 0.01% Vaginal Cream (VersaBase®)
  – PCCA Formula #12031 - Estriol/Estradiol [50%/50%] 0.5 mg/0.5 Gm Vaginal Gel (MucoLox™/VersaBase®)
  – PCCA Formula #12032 - Estriol 0.1%/Testosterone 0.1% Vaginal Gel (MucoLox™/VersaBase®)
Estradiol 10mg/Gm Dilution & Estriol 10mg/Gm Dilution

- **Formulation examples (topical and vaginal preps only)**
  - PCCA Formula #12033 - Estriol 0.05% Vaginal Gel (MucoLox™/VersaBase®)
  - PCCA Formula #12036 - Estriol 0.2% / Vitamin A Palmitate 0.3% / Vitamin E Acetate 0.6% Chrysaderm Night Topical Cream
  - PCCA Formula #12037 - Estriol 0.1% / Palmitoyl Pentapeptide 5% / Acetyl Hexapeptide 15% Eye Cream
MucoLox™ is a polysaccharide mucosal delivery system
- Patent pending
- Unique synergy between Pullulan, Tamarind Xyloglucan, Zea Mays Starch and Sodium Hyaluronate
- Designed to improve API contact time on mucosal surfaces.
- Polysaccharides are highly stable, safe, non toxic, hydrophilic and biodegradable
Topical Application of Control Product
Topical Application of MucoLox™ Pilot

5 min

10 min

401 min

Gel

Tissue area

Microporous membrane

Gel

Microporous membrane

Gel

Tissue area

Microporous membrane

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Evaluation of the Vaginal Safety and Toxicological Profile of MucoLox™

- MucoLox™ exerts minimal toxicity on the vaginal mucosa following over 20 hours of exposure.
- Document #98930
Conditions in Women’s Health that May Benefit from Prolonged Contact of the Active Pharmaceutical Ingredient

- Genital herpes
- Genital warts
- PCOS
- Endometriosis
- Infections
- Vaginal dryness

- Vaginal itching
- Vulvodynia
- Lichen sclerosus
- Anal fissures
- Hemorrhoids
Compounding Opportunities for Genital Herpes

- Prolonged contact of the API may provide benefit
- Combination therapy is often requested for pain control
Compounding Opportunities for Genital Herpes

• Skyrocketing commercial drugs prices for herpes
  – Brand name cream cost to pharmacy could be >$650 for 5 grams!!! (no generic for the cream)
  – Brand name ointment cost to pharmacy could be almost $1200 for 30 grams
  – Acyclovir ointment cost to pharmacy may be anywhere from $280-$650 for 30 grams (depends on contract but average may be >$400)

• Considerations:
  – May be rejected by insurance
  – Copay may make it unaffordable for patient
Compounding Opportunities for Genital Herpes

- Compounded alternative
  - #11413 Acyclovir 5% / Lidocaine HCl 5% / Deoxy-D-Glucose 2% Vaginal Gel (MucoLox™)
Genital Warts

- PCCA Formula #11111 - Fluorouracil (5-FU) 5% Topical Gel (MucoLox™ / VersaBase®)
- PCCA Formula #11112 - Imiquimod 0.5% Vaginal Gel (MucoLox™ / VersaBase®)
- PCCA Formula #11415 - Deoxy-D-Glucose 0.2% / Acyclovir 5% / Imiquimod 2.5% / Tea Tree Oil 2.5% Vaginal Gel (MucoLox™ / VersaBase®)
  - PCCA Document #98856 - Multi-Therapy Use of Topical Imiquimod & Formulas
• Xerese®
  – Acyclovir 5% + hydrocortisone 1% cream
  – A patient requested a petrolatum-free base
  – 5 grams cost to pharmacy around 1K
• PCCA Formula #11989 - Acyclovir 5% / Lidocaine 2% / Hydrocortisone 2.5% Topical Cream (VersaBase®)
PCOS

• Metformin - GI side effects when taken orally; patients are often unable to tolerate it
• PCCA Formula #11542 - Metformin HCl 10% Vaginal Gel (MucoLox™)
• PCCA Formula #10871 - Metformin HCl 10% Topical Lipoderm®
PCOS

• PCCA Document #98749 - Transdermal Metformin - Consultant's Corner by Jane Jones (02-14 + 11-15 Apothagram)
• PCCA Document #98746 - PCOS Nutritional References
• PCCA Document # 98833 - Video on Demand: PCOS, Endometriosis, and Sleep Disorders in Menopause
Endometriosis

- PCCA Formula #11946 - Progesterone 10% Vaginal Gel (MucoLox™)
- PCCA Formula #11950 - Danazol 10% Vaginal Gel (MucoLox™)
- PCCA Document #98746 PCOS Nutritional References
- PCCA Document #98833 Video on Demand: PCOS, Endometriosis, and Sleep Disorders in Menopause
Pelvic Pain

• Various potential causes
• Lack of topical / vaginal commercial options
• Combination gels used vaginally can offer a variety of mechanisms of action
  – PCCA Formula #11114 - Diazepam 10 mg/Gm Vaginal / Rectal Gel (MucoLox™ / VersaBase®) (BUD Study)
  – PCCA Formula #11109 - Ketamine HCl 0.5%/Diazepam 1%/Baclofen 2% Vaginal Gel (MucoLox™ / VersaBase®)
  – PCCA Formula #11946 - Progesterone 10% Vaginal Gel (MucoLox™)
Pelvic Pain (cont’d)

• Transdermal pain creams may be an option in some cases; apply externally
  – PCCA Document #9874 - Ketoprofen 10% / Cyclobenzaprine HCl 2% Topical Lipoderm® (BUD Study)
  – PCCA Document #9380 - Ketoprofen 5% / Cyclobenzaprine HCl 0.5% / Lidocaine HCl 5% / Bupivacaine HCl 1% Topical Lipoderm®
Vaginal Infections

• Recurrent vaginal infections
  – Commercial options tried first to treat the actual infection
    • Boric acid
      – PCCA Formula #11368 - Boric Acid 30% Vaginal Gel (MucoLox™)
      – PCCA Formula #11367 - Boric Acid 600 mg Base MBK / MucoLox™ Vaginal Suppository (Pink Mold)

• Resistant infections
  – Yeast (Candida glabrata, resistant C tropicalis)
Vaginal Infections

- Increased contact time to the mucosa may be beneficial
- Metronidazole vaginal gel
- 70 grams cost to pharmacy is around $100
- PCCA Formula #11994 - Metronidazole 0.75% Vaginal Gel (MucoLox™ / VersaBase®)
Vaginal Infections

• Recurrent vaginal infections
  – Commercial options often tried first to treat the actual infection before recurrence
  • Boric acid
    – #11368 - Boric Acid 30% Vaginal Gel (MucoLox™)
    – #11367 - Boric Acid 600 mg Base MBK / MucoLox™ Vaginal Suppository (Pink Mold)
Flucytosine

• Commercial option for cream not available
• Per the study in the treatment of Candida glabrata and Candida tropicalis: #14 500mg capsules needed to make (only) 45 grams of cream
• Cost to pharmacy to purchase 500mg x 100 caps (to only use #14 per Rx) may be around $11,000
  – Insurance rejection or unaffordable copay
• #11113 - Flucytosine 15% Vaginal Cream (MucoLox™ / VersaBase®)
Vaginal Dryness

• Patients asking for alternatives
  – Concern over hormones
  – Non-hormonal options
• Practitioners are aware of estriol and benefits; not commercially available
Vaginal Dryness (cont’d)

• Skyrocketing commercial drug products
  – Conjugated estrogen: not bioidentical
  – Estradiol vaginal cream (commercial)
  – 42.5 gram tube cost to the pharmacy is over $250
    • There are no generic options
    • Insurance rejection
Vaginal Dryness (cont’d)

• Compounded alternatives
  – PCCA Formula #11115 - Estriol 0.05% Vaginal Gel (MucoLox™ / VersaBase®)
  – PCCA Formula #11724 - Oxytocin 120 U/Gm Vaginal Gel (MucoLox™ / VersaBase®)
  – PCCA Formula #11118 - Sodium Hyaluronate 5 mg/Gm Compound Vaginal Gel (MucoLox™ / VersaBase® Gel)
  – PCCA Formula #11119 - Vitamin E 200 U/Gm Vaginal Gel (MucoLox™ / VersaBase®)
Vaginal Dryness (cont’d)

- New studies with ‘ultra’ low-dose estriol
  - Vaginal atrophy
  - Significantly improved the growth of the vaginal mucosa
  - Sexual health
  - Quality of life for women
  - Vulvodynia and interstitial cystitis / bladder pain syndrome (IC / BPS).
Vaginal Dryness (cont’d)

• Formulation ideas
  – PCCA Formula #12124 - Estriol 0.03 mg/Gm / Acidophilus 10 MU/Gm Vaginal Gel (MucoLox™ / VersaBase®) (PCCA Dilution)
  – PCCA Formula #12123 - Estriol 0.005% Vaginal Gel (MucoLox™ / VersaBase®) (PCCA Dilution)
  – PCCA Formula #12124 - Estriol 0.03 mg/Gm / Acidophilus 10 MU/Gm Vaginal Gel (MucoLox™/VersaBase®) (PCCA Dilution)
Vaginal Itching

• There could be many reasons for itching; practitioners and patients often seek options after traditional treatments have been tried
• Moisturizing base may provide a benefit
• Multi drug therapy in a compounded base may be beneficial especially if cause is unknown
Vaginal Itching (cont’d)

• Skyrocketing drug prices
  – Common commercial compound Rx often unavailable
    • Crotamiton / betamethasone commercial products often unavailable to patients
      • A 60 gram tube cost to the pharmacy is close to $500

• Compounded alternatives
  – PCCA Formula #11887 - Tranilast 1% / Betamethasone 0.05% Topical Gel (MucoLox™ / VersaBase®)
  – PCCA Formula #11575 - Ketotifen 0.4% Vaginal Gel (MucoLox™ / VersaBase®)
Vulvodynia

• Prolonged contact time with the mucosa and multi-drug therapy may be beneficial to try help with pain
  – PCCA Formula #11108 - Amitriptyline HCl 2% / Baclofen 2% Vaginal Gel (MucoLox™)
  – PCCA Formula #11109 - Ketamine HCl 0.5% / Diazepam 1% / Baclofen 2% Vaginal Gel (MucoLox™ / VersaBase®)
  – PCCA Formula #11110 - Gabapentin 6% Vaginal Gel (MucoLox™ / VersaBase®)
Lichen Sclerosus

- Prolonged contact time may be helpful for delivery of active pharmaceutical ingredients
- PCCA Formula #11751 - Tacrolimus 0.03% Vaginal Gel (MucoLox™ / VersaBase®)
  - Tacrolimus 0.1% ointment was applied twice daily for 6 weeks, then tapered over the following 6 weeks.
  - Commercial product choices: 100 grams close to $550!
- PCCA Formula #11884 - Clobetasol Propionate 0.05% Vaginal Gel (MucoLox™ / VersaBase®)
Anal Fissure

• Compounding treatment options
  – PCCA Formula #11124 - Nifedipine 0.2% Rectal Gel (MucoLox™ / VersaBase®)
  – PCCA Formula #11952 - Nifedipine 0.2% / Lidocaine HCl 2% Rectal Gel (MucoLox™)
Hemorrhoids

- PCCA Formula #11954 - Pramoxine HCl 1% / Zinc Oxide 12.5% / Lidocaine HCl 5% Topical Gel (MucoLox™)
- PCCA Formula #11491 - Lidocaine 2% / Hydrocortisone 1% Base MBK / Wax / MucoLox™ Suppository (Rectal Rocket)
Female Sexual Dysfunction
Female Sexual Dysfunction

• PCCA Formula #11947 - Testosterone 0.2% Vaginal Gel (MucoLox™)
• PCCA Formula #11948 - Sildenafil 1% / Testosterone 0.1% Topical Gel (MucoLox™)
Female Sexual Dysfunction

- PCCA Formula #11386 - Dehydroepiandrosterone 13 mg/Gm Vaginal Gel (MucoLox™ / VersaBase®)
- PCCA Formula #10879 – Papaverine 0.1% / Arginine 6% Topical Lipoderm®
- PCCA Formula #9295 - Sildenafil 1% / Arginine HCl 11.7% / Naltrexone HCl 0.817% Topical Cream (VersaBase®)
• PCCA document #97920 - Compounding Ideas / Formulations Marketing Sheet - Female Sexual Dysfunction & Libido

• PCCA Document 98289 - Treatment Options for Vaginal Atrophy: What Do the New Studies Show? by Annie DeReese (Consultant's Corner, 01-11 Apothagram)
Thank You

Questions