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PRESRIPTION COMPOUNDING FOR

OBSTETRICS & GYNECOLOGY

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**ATROPHIC VAGINITIS**

The following clinical study finds that vaginal administration of hyaluronic acid or estradiol were both effective in treating atrophic vaginitis - “The comparison of hyaluronic acid vaginal tablets with estradiol vaginal tablets in the treatment of atrophic vaginitis: a randomized controlled trial” (Arch Gynecol Obstet. 2010 Feb 5).

**OBJECTIVE:** To compare the effectiveness of the vaginal tablets of hyaluronic acid and estradiol for the treatment of atrophic vaginitis.

**MATERIALS AND METHODS:** Forty-two postmenopausal women with symptoms of atrophic vaginitis were randomized to take vaginal tablets of 25 mcg estradiol (n = 21) (group I) or 5 mg hyaluronic acid sodium salt (n = 21) (group II) for 8 weeks. The symptoms of atrophic vaginitis were evaluated by a self-assessed 4-point scale of composite score and the degree of epithelial atrophy was determined as, none, mild, moderate and severe. Vaginal pH and maturation index were measured and compared in both the groups.

**RESULTS:** The symptoms were relieved significantly in both the groups (P < 0.001). The relief of symptoms was significantly superior in group I compared with group II (P < 0.05). A significant decrease in epithelial atrophy and vaginal pH were detected in both the groups (P < 0.01) after treatment. The vaginal maturation values were also significantly improved at both study groups (P < 0.001). The mean maturation value was significantly higher in group I when compared with group II (P < 0.001).

**CONCLUSION:** Both treatments provided relief of vaginal symptoms, improved epithelial atrophy, decreased vaginal pH, and increased maturation of the vaginal epithelium. Those improvements were greater in group I. Hyaluronic acid vaginal tablets can be used in patients with atrophic vaginitis who do not want to or cannot take local estrogen treatment. PMID: 20135132

With our state of the art compounding laboratory and pharmaceutical knowledge and experience, we have the ability to compound estradiol or hyaluronic acid (sodium hyaluronate) into separate vaginal suppositories.

Examples of how you might prescribe follow:

<table>
<thead>
<tr>
<th>COMPOUNDED MEDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol 25mcg</td>
</tr>
<tr>
<td>Vaginal Suppository</td>
</tr>
<tr>
<td>#30</td>
</tr>
<tr>
<td>Insert 1 suppository vaginally QD or as directed</td>
</tr>
<tr>
<td>or</td>
</tr>
<tr>
<td>Sodium Hyaluronate 5mg</td>
</tr>
<tr>
<td>Vaginal Suppository</td>
</tr>
<tr>
<td>#30</td>
</tr>
<tr>
<td>Insert 1 suppository vaginally QD or as directed</td>
</tr>
</tbody>
</table>
RAYNAUD'S OF THE NIPPLE

The following case report suggests that patients with episodic nipple pain and pallor can be successfully treated with nifedipine - “Vasospasm of the nipple presenting as painful lactation” (Obstet Gynecol. 2006 Sep;108(3 Pt 2):806-8).

BACKGROUND: Breast pain is a common complaint among lactating women. Vasospasm of the nipple should be considered in the differential diagnosis of breast pain, particularly when no other signs of infection or trauma are encountered. This report demonstrates a case of vasospasm successfully treated with nifedipine.

CASE: A 26-year-old breastfeeding multipara presented with intermittent episodes of extreme pain associated with blanching of the nipple. The pain subsided upon return of normal color to the nipple. She was able to continue breastfeeding after successful treatment with nifedipine.

CONCLUSION: Vasospasm of the nipple causes severe episodic breast pain and may lead to discontinuation of breastfeeding if not appropriately treated. This phenomenon is not well reported in the obstetric and gynecologic literature, although the obstetrician may be the first physician to evaluate a patient with symptoms. Patients with episodic nipple pain and pallor can be successfully treated with nifedipine. PMID: 17018510

This case report highlights treating nipple vasospasms related to Raynaud’s with nifedipine - “Nipple vasospasms, Raynaud’s syndrome, and nifedipine” (J Hum Lact. 2002 Nov;18(4):382-5).

ABSTRACT: “This case report describes a situation in which a mother who experienced prolonged nipple pain with her first child sought help from a lactation consultant at the birth of her second child. Despite being very attentive to positioning and latch, similar pain was experienced from the first feeding with the second baby. The mother's history and symptoms were explored, and nipple vasospasms related to Raynaud's syndrome were suspected. After reviewing the literature and consulting with her personal obstetrician, the mother (a pediatrician) chose to treat with nifedipine. The mother was pain free after a 2-week course and nursing without difficulty at 4 months postpartum.” PMID: 12449056

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound a topical version of nifedipine that may allow for a dramatically lower dose (vs. oral administration), and cause far fewer systemic side effects.

An example of how you might prescribe follows:

**COMPounded MEDICATION**

**Nifedipine 0.2%**  
Topical Cream  
30gm  
Apply sparingly BID-TID
ANAL FISSURES

The following review concludes that topical diltiazem is effective in treating anal fissures and is associated with fewer side effects than glyceryl trinitrate - “The efficacy of diltiazem and glyceryl trinitrate for the medical management of chronic anal fissure: a meta-analysis” (Int J Colorectal Dis. 2008 Jan;23(1):1-6).

OBJECTIVE: The objective of this review is to systematically analyze the prospective randomized controlled trials on the effectiveness of diltiazem (DTZ) and glyceryl trinitrate (GTN) for the pharmacological management of chronic anal fissure (CAF).

MATERIALS AND METHODS: A systematic review of the literature was undertaken. Prospective randomized controlled trials on the effectiveness of DTZ for the management of CAF were selected according to specific criteria and analyzed to generate summative data.

RESULTS: Five studies encompassing 263 patients with CAF were retrieved from the electronic databases. Only two randomized controlled trials on 103 patients were included in the meta-analysis. There were 53 patients in the DTZ group and 50 patients in the GTN group. Both DTZ and GTN were equally effective for the treatment of CAF (random-effect model risk ratio [RR] 0.29 [90.06-1.33] 95% confidence interval [CI], z = 0.62, p = 0.536). However, there was significant heterogeneity between the trials. GTN was associated with a higher rate of side effects (fixed-effect model RR 0.45 [0.28-0.73] 95% CI, z = -3.22, p = 0.001) and higher headache rate (fixed-effect model RR 0.33 [0.17-0.64] 95% CI, z = -3.27, p = 0.001) as compared to DTZ. There was no statistically significant recurrence rate of CAF between two pharmacotherapies (fixed-effect model RR 0.66 [0.18-2.41] 95% CI, z = -0.62, p = 0.535).

CONCLUSIONS: Both DTZ and GTN are equally effective and can be used for the management of CAF. However, GTN is associated with a higher rate of side effects (headache/anal irritation), and it should be replaced by DTZ. The recurrence rate of CAF after the use of both pharmacotherapies is equal. PMID: 17846781

The following study found that topical diltiazem does not have the side effects of nitroglycerin and is better accepted by patients - “Local treatment of a chronic anal fissure with diltiazem vs. nitroglycerin. A comparative study” (Cir Esp. 2010 Apr;87(4):224-30).

AIM: To assess the value of using smooth muscle relaxants drugs and assess the results of the topical use of 2% diltiazem as an alternative to 0.2% nitroglycerin in the treatment of chronic anal fissure (CAF).

METHODS: Review of the CAF contained in a prospectively collected database of anal fissures including one hundred forty-five patients diagnosed with CAF and treated with standard measures (ST) in two consecutive periods. During the first period they were allocated alternatively to not receive further treatment (ST group) or to be treated with nitroglycerin ointment (NTG group). In the second period all were treated with local diltiazem (DTZ group). One hundred forty-five patients entered the study and 124 completed it.

RESULTS: Initially there were significant differences in improvement rates (45% ST, 62.5% NTG and 80% DTZ, p<0.01), but not in the cure rates (27% ST, 40% NTG and 39% DTZ) and the treatment was completed by 124 patients (85.5%). There were more side effects and more dropouts in the NTG group. In the subsequent follow-up for a median period of 25 months there were 25% recurrences and almost all responded to repeated medical treatment.

CONCLUSIONS: Smooth muscle relaxant drugs do not achieve a higher cure rate than the traditional measures used in CAF, but offer more symptomatic relief, providing an opportunity to avoid surgery. Topical diltiazem does not have the side effects of the nitroglycerin and is better accepted by patients. PMID: 20206340

An example of how you might prescribe follows:

With our state of the art compounding lab pharmaceutical knowledge and experience, we can compound diltiazem as a topical gel.

COMPOUNDED MEDICATION

| Diltiazem 2%  
Topical Gel  
30gm  
Apply TID |
Atrophic Vaginitis

[ ] Estradiol 25mcg Vaginal Suppository
Quantity #30 Directions: Insert 1 suppository vaginally QD as directed

[ ] Sodium Hyaluronate 5mg Vaginal Suppository
Quantity #30 Directions: Insert 1 suppository vaginally QD as directed

Raynaud’s of the Nipple

[ ] Nifedipine 0.2% Topical Cream
Quantity 30gm Directions: Apply sparingly BID-TID

Anal Fissures

[ ] Diltiazem 2% Topical Gel
Quantity 30gm Directions: Apply TID

Directions


Prescriber’s Signature__________________________ Refills: 1 2 3 4 5 6 7 8 9 10 11 12 NR

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