Assessing the clinical effectiveness of an algorithmic approach to mucosal lichen planus: a retrospective review

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Conflicts of Interest

- The authors declare no conflicts of interest or financial disclosures
Mucosal Lichen Planus (MLP)

- Chronic autoimmune disorder
- Affects mucosal membranes in the body
- Often causes debilitating pain
- Differential diagnosis is broad
- Prevalence is $\sim 1\%$
- More frequently found in women 30-60 years old
- Requires long term follow-up
The Problem

- No immediate cure for MLP patients\(^2\)
- A therapeutic challenge to dermatologists
- Various therapeutic modalities
  - Currently, topical corticosteroids are the mainstay of therapy\(^2,3\)
  - Combination treatments have been tried\(^4\)
- High quality evidence is lacking for the treatment of MLP
  - Treatment is not standardized
  - No Gold-Standard treatment regimen\(^2,5\)
Our Stepwise Treatment Plan
### STEP 1: Topical Steroids/Calcineurin Inhibitor
- Most patients initially
- Mild pain, disease activity and number of lesions
- Shorter duration of disease

### STEP 2: Step 1 + Prednisone Burst/Taper (Start at 40mg/day)
- Oral and genital lesions
- Severe oral disease, present for multiple years
- Acute exacerbation

### STEP 3: Step 2 + Mycophenolate mofetil (500mg-2g/day)
- Severe oral disease: multiple sites, severe pain
- Pruritus, bleeding, unable to eat
- Oral and genital involvement

### STEP 4: Step 3 + Cyclosporine (4mg/kg/day)
- Severe oral and genital
- Severe genital only
- Not improving on CellCept
Hypothesis

1. Our treatment plan results in:
   - Decreased disease activity
   - Decreased pain
   - Decreased number of lesions

2. Mycophenolate mofetil is efficacious and has a higher safety profile in MLP patients
Methods

- Retrospective review of paper + electronic medical records
- Approved by MSU IRB (#14-1071)
- N = 53
  - Total of 4 patients not included in statistical analysis
    - 3 patients only had initial visits
    - 1 patient did not have data from their initial visit
### Methods

#### Inclusion Criteria
- Ages 18-89
- M and F
- Diagnosed by a dermatologist, oral med or genitourinary physician, gynecologist
- Treated w/ regimen between 1990-2014

#### Exclusion Criteria
- Idiopathic
- Plaque-like lichen planus (non-erosive)
- Lichenoid drug eruptions
Disease Severity Variables

Three Variables

1. # of disease sites/locations
2. Disease activity
3. Pain reported

- **Disease Activity**
  - 0 = not inflamed/keratosis only
  - 1 = mildly inflamed
  - 2 = inflamed
  - 3 = erosion

- **Pain Reported**
  - 0 = None
  - 1 = Mild
  - 1.5 = Mild to Moderate
  - 2 = Moderate
  - 2.5 = Moderate to Severe
  - 3 = Severe
Methods

● **Mycophenolate mofetil Protocol**
  ○ In accordance with office protocol

● **Statistical Analysis**
  ○ Frequency tables were used to describe clinical findings and demographic characteristics.
  ○ Values for our three variables at the last visit (n = 49) were compared with baseline scores (n = 49) determined at the initial visit to DAWM office using the Wilcoxon matched pairs signed-rank test and paired samples t-test.
  ○ Statistical significance was assumed with a P-value <0.05.
Results
### Cohort Statistics

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients in study</td>
<td>53</td>
</tr>
<tr>
<td>Male</td>
<td>16 (30%)</td>
</tr>
<tr>
<td>Female</td>
<td>37 (70%)</td>
</tr>
<tr>
<td>Mean age</td>
<td>60 (34-84)</td>
</tr>
<tr>
<td>Autoimmune skin disease</td>
<td>19 (36%)</td>
</tr>
<tr>
<td>Mean duration of treatment</td>
<td>4 years</td>
</tr>
<tr>
<td>Step 1</td>
<td>3 years</td>
</tr>
<tr>
<td>Step 2</td>
<td>2 months</td>
</tr>
<tr>
<td>Step 3</td>
<td>8 months</td>
</tr>
<tr>
<td>Step 4</td>
<td>1 week</td>
</tr>
<tr>
<td>Patients on each step</td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
<td>44 (85%)</td>
</tr>
<tr>
<td>Step 2</td>
<td>23 (44%)</td>
</tr>
<tr>
<td>Step 3</td>
<td>22 (42%)</td>
</tr>
<tr>
<td>Step 4</td>
<td>2 (0.04%)</td>
</tr>
<tr>
<td>Presentation</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>36 (68%)</td>
</tr>
<tr>
<td>Genital</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Both</td>
<td>14 (26%)</td>
</tr>
</tbody>
</table>
Step Started at Initial Visit and at End of study

### Step at Initial Visit
- Step 1: 37 (71%)
- Step 2: 12 (23%)
- Step 3: 3 (6%)

### Step at End of study
- Step 1: 32 (63%)
- Step 2: 13 (25%)
- Step 3: 4 (8%)
- Step 4: 2 (4%)
- None: 4 (8%)
Number of lesions, pain reported, and disease activity at first and last visit of study
Number of lesions, pain reported, and disease activity at first and last visit of study stratified by MM use
Discussion

1. Our standardized treatment plan:
   ○ Reduces # of MLP lesions by an average of 2 \( (p<0.001) \)
   ○ Reduces disease activity by 1.8 points \( (p<0.001) \)
   ○ Reduces pain by an average of 1 point \( (p<0.001) \)

2. Mycophenolate Mofetil therapy is safe and efficacious in our patient population
   ○ 22 patients, treated at lower doses, <3g
   ○ Followed closely per protocol
   ○ 6 pts 100% clear after stepwise treatment
   ○ 68% improved, 14% no change, 9% worsened
   ○ 8 pts experienced mild side effects`, 3 discontinued use
Study Limitations

● No universal severity scale
● Our scale was retrospectively applied
  ○ Data documented by the same dermatologist for each patient/visit
  ○ One researcher categorized the patients
● Limitation to future studies:
  ○ Scale
  ○ No Gold-Standard treatment for control
  ○ Ethicality of Placebo
References