Introduction

• Package labeling lists pain associated with post-herpetic neuralgia (PHN) as the sole indication for the use of transdermal lidocaine 5% patch (L5P)

• Questionable efficacy in non-labeled neuropathy and musculoskeletal pain conditions has been reported

• In a randomized, double-blind, placebo-controlled brain imaging study, L5P demonstrated that it is no more potent than placebo in treating chronic back pain1

• Another study showed that L5P does not significantly improve pain control in polytrauma patients with traumatic rib fractures3

• Postoperatively, the concurrent use of L5P in the treatment of patients after total knee arthroplasty does not provide significant additional pain relief compared with control subjects1

• Currently in our health system, there are no medication guidelines limiting the use of L5P

Objectives

Primary Objective

• To characterize the label and off-label use of L5P in our health system

Secondary Objectives

• To evaluate effectiveness of L5P for label and off-label use

• Assess documented improvement due to L5P

• Identify adherence to adverse events

• To evaluate safety of L5P

• Identify presence of adverse events

Methods

• This study is a retrospective chart review approved by the Institutional Review Board at BHS

• The electronic medical record system was used to generate a list of all patients receiving L5P at multiple sites within our health system

• The first fifty patients from each site on the list (Royal Oak, Troy, Grosse Pointe), from June 1, 2013 through June 30, 2013, were included in the study

• The electronic medical record was reviewed for patient-specific information including age, weight, gender, indication for L5P use, and length of stay

• Order-specific information was collected including prescriber name, duration of therapy, start and stop date, frequency of application, and reason for discontinued therapy

• Pain medication use prior to admission, during inpatient visit, and at discharge were reviewed

• Patient-reported pain scores and healthcare provider chart documentation were collected to assess efficacy of L5P

• Adequate efficacy, naloxone administration, and rapid response or cardiopulmonary resuscitation calls were collected to assess safety of L5P

• Descriptive statistics were used for many of the data endpoints. Correlation statistics were performed using Pearson Product Moment Correlation. Correlation statistics were done using SigmaPlot statistics software (SigmaStat 11.1, Systat Software, Inc., Chicago, Illinois, USA)

Results

Table 1. Baseline Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n=118</th>
<th>±</th>
<th>SD</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD, years</td>
<td>65 (28%)</td>
<td>3.9±3.0 (1-15)</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Length of stay (LOS), days</td>
<td>5 (1-15)</td>
<td>6</td>
<td>92 (78%)</td>
<td></td>
</tr>
<tr>
<td>Weight, mean ± SD, kg</td>
<td>70±27</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2. L5P Inpatient Use

<table>
<thead>
<tr>
<th>Date Administered</th>
<th>Case Count</th>
<th>Total Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 Days</td>
<td>111</td>
<td>3.2±2.7 (0-15)</td>
</tr>
<tr>
<td>3-4 Days</td>
<td>1</td>
<td>3.9±3.0 (1-15)</td>
</tr>
</tbody>
</table>

Table 3. L5P Safety Endpoints

<table>
<thead>
<tr>
<th>Adverse Drug Effects</th>
<th>n=118</th>
<th>±</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Hypersensitivity</td>
<td>9 (7.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>7 (6.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>4 (3.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (1.7%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4. L5P Adverse Drug Effects

<table>
<thead>
<tr>
<th>% of Patients</th>
<th>n=118</th>
</tr>
</thead>
<tbody>
<tr>
<td>Of the patients studied no naloxone was administered after patch application. One patient required cardiopulmonary resuscitation not due to L5P application</td>
<td></td>
</tr>
<tr>
<td>We found no significant relationship between median daily pain score and documented improvement</td>
<td></td>
</tr>
<tr>
<td>Approximately 7% of patients (n=8/118) did not receive an accurate dose as prescribed by the physician</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions

• L5P at Beaumont Health System is primarily used for back pain despite there being little evidence in literature supporting its use for any indication other than PHN

• The use of L5P for the indication of PHN at BHS only accounts for 3% of its total use

• Eighteen percent of patients (n=21/118) had documented improvement in the chart due to L5P application

• Pain score not correlate with documented improvement

• Correlation of PHN versus other indications with pain scores could not be analyzed with only four patients (1.7%) in the data set

• During review of medication orders, nurse-administration instructions had pre-populated instructions that were not found to be clinically relevant or consistent with standard practice

• L5P was administered 0.7 days less than ordered

Future Directions

• Report study findings to the Pain Clinical Integration Council and Medication Management Committee (Pharmacy and Therapeutics Committee at BHS)

• Create a medication guideline indicating appropriate use of L5P

• Provide education to medical staff regarding new medication guidelines

• Request update of physician order entry for L5P to clarify administration instructions

References


Limitations

• Convenient sample size, (n=118)

• Retrospective chart review design

• Reports generated to identify study subjects could have led to incomplete recruitment of all eligible patients

• Pain assessment documentation was not consistent more detailed, possibly leading to inaccurate characterization of pain control. Inconsistent assessment may have lead to reduced clinical effect

DISCLOSURES

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject of this presentation:

Olga Kishhek: Nothing to disclose

Erin Baker: Nothing to disclose

Levi Hall: Nothing to disclose