The Clinical Utility, Safety, and Tolerability of Poly L-lactic Acid Injections for HIV-Related Facial Lipoatrophy at the San Francisco VA Medical Center

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The development of facial lipoatrophy (LA) in the setting of antiretroviral therapy has been associated with decreased quality of life and adherence to life-prolonging antiretroviral therapy. Poly L-lactic acid (PLLA) injections were recently FDA approved for HIV-related LA. The study evaluated the safety and tolerability of PLLA in HIV-infected patients with moderate and severe lipoatrophy. Eligibility for PLLA was established using a standardized clinical assessment of LA severity: Grade 1 (mild lipoatrophy), Grade 2 (moderate lipoatrophy), and Grade 3 (severe lipoatrophy) by an independent panel of at least 1 infectious disease physician and 1 registered diabetologist experienced in the management of lipoatrophy. Of 16 patients who self-reported from the ID Clinic, 8 patients were identified as having an average LA score ≥2 and referred to a dermatologist with expertise in PLLA for at least 3 monthly injections. We describe the outcomes of HIV-infected patients who received PLLA injections using objective measures including changes in facial anthropometry, QOL, and actual facial features. The cost of PLLA coverage for our clinic has been surprisingly low because of the identification of relatively few patients with moderate to severe facial lipoatrophy, possibly because delayed access to this intervention led to patients seeking treatment in non-VA health care settings.

Abstract

The development of facial lipoatrophy (LA) in the setting of antiretroviral therapy has been associated with decreased quality of life (QOL) and adherence to life-prolonging antiretroviral therapy. Poly L-lactic acid (PLLA) injections were recently FDA approved for HIV-related LA, but the cost of therapy (on average $8000 per patient for 4 monthly sessions) may be prohibitive in publicly funded HIV clinics. At the SFVAMC, facial LA was identified as a common complaint of HIV-infected patients seen in the Infectious Diseases (ID) Clinic. We obtained funding to provide PLLA injections to HIV-infected patients with moderate and severe lipoatrophy. Eligibility for PLLA was established using a standardized clinical assessment of lipoatrophy [1]. There were 3 monthly assessment visits: at 1, 2, and 3 months after treatment. PLLA was administered using a standardized clinical assessment of lipoatrophy [1]. The results were analyzed using paired t-tests and Fisher's exact test for categorical variables. The results showed a significant improvement in facial appearance and QOL. The mean QOL score improved by week 16, baseline scores ranged from -10 to +50, mean +17; week 16 scores +11 to +51, mean +37. The average number of treatments anticipated for these 8 patients was 4.5. The development of PLLA is an effective short-term treatment for patients with HIV-related lipoatrophy in the VA system. Facial anthropometry appears to be a useful objective measure of facial lipoatrophy change in response to PLLA treatment. QOL measures significantly improved in the treated population. GLSS and digital photography appear to be useful adjunctive clinical measures for severity of LA and response to treatment.

Methods (con’t)

Background

Results (con’t)

Population 16 HIV patients with facial lipoatrophy, referred from the ID clinic at SFVAMC.

Eligibility established using the Global LA severity score (GLSS3) [5] - Normalized LA score by at least 1 infectious disease physician and 1 registered diabetologist

Figure 1: Global Lipoatrophy Severity Score

Table 1:

<table>
<thead>
<tr>
<th>Patient</th>
<th>Baseline GLSS score</th>
<th>Change from Baseline Measurements</th>
<th>GLSS score</th>
<th>Fat fold (mm)</th>
<th>Difference</th>
<th>Total Treatment Planned</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.8</td>
<td>+0.3</td>
<td>2.1</td>
<td>0.0</td>
<td>4.0</td>
<td>1.5</td>
</tr>
<tr>
<td>2</td>
<td>2.0</td>
<td>+0.5</td>
<td>2.5</td>
<td>0.0</td>
<td>4.0</td>
<td>0.0</td>
</tr>
<tr>
<td>3</td>
<td>2.2</td>
<td>-2.2</td>
<td>2.0</td>
<td>0.0</td>
<td>4.0</td>
<td>2.0</td>
</tr>
<tr>
<td>4</td>
<td>2.0</td>
<td>+1.5</td>
<td>3.5</td>
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<tr>
<td>5</td>
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<tr>
<td>6</td>
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<tr>
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<tr>
<td>8</td>
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</tr>
</tbody>
</table>

Average: 2.2 -1.1 1.0 4.6 2.1 4.6

• BIQLI QOL scores improved by week 16, baseline scores ranged -10 to +50, mean +17; week 16 scores +11 to +51, mean +37
• The average number of treatments anticipated for these 8 patients was 4.5.
• The average total cost of treatment per patient (given acquisition cost of $960 per treatment) was $4320, leading to a total cost of treatment for these 8 patients of $34,560.

Conclusions

5. Adapted from SJ Moyse’ study in Chelsea and Westminster Hospital, London
6. Cash TF, Fleming EC. 2002. The impact of body-image experiences: Development of the Body Image Quality of Life Inventory. Int J Eating Disorders 34:09.03.00.05

References

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