Patient-Reported Outcomes regarding adalimumab new formulation

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BACKGROUND

Adalimumab is currently available in a 40mg/0.4mL formulation with fewer excipients, smaller volume and gauge needle, versus 40mg/0.8mL previous formulation.

PURPOSE

To evaluate injection site-related pain (ISRP) and satisfaction of new adalimumab formulation in comparison with previous one.

MATERIALS AND METHODS

Observational, prospective, analytical study (April-September 2017) in Outpatient Pharmacy Departments of two General Hospitals. We selected patients on adalimumab treatment who changed old formulation to new formulation, and had been with new one at least two months. Data collection interview comprised: sex, age, immune disease, old formulation treatment time, and a questionnaire about the person who administers adalimumab, injection sites, warm up drug before administration moment, ISRP with Visual Analogue Scale (VAS) and satisfaction with adalimumab new formulation. Data were analyzed with SPSS® v.21.

RESULTS

75 patients (pat.) were included, 46 (65.3%) male, mean age 49.8±13.5 years.

Old formulation treatment time

<table>
<thead>
<tr>
<th>Disease</th>
<th>Nº of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uveitis</td>
<td>4</td>
</tr>
<tr>
<td>Psoriatic Arthritis</td>
<td>11</td>
</tr>
<tr>
<td>Ulcerative Colitis</td>
<td>18</td>
</tr>
<tr>
<td>Ankylosing Spondylitis</td>
<td>72</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>23</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>18</td>
</tr>
<tr>
<td>Crohn’s disease</td>
<td>18</td>
</tr>
</tbody>
</table>

Person who administers adalimumab

- Auto-administration: 2% (2/75)
- Familiar support: 75% (56/75)
- Nurse support: 23% (17/75)

Chi-square test did not show statistically significant differences between:
- ISRP absence and auto-administration (p=0.567)
- Warm up and ISRP absence (p=0.404)
- Satisfaction and ISRP absence (p=0.673).

Patients who warm up drug before administration

- Always: 70.7% (53/75)
- Sometimes: 14.7% (11/75)
- Never: 14.7% (11/75)

52 pat. (69.3 %) without ISRP
Mean VAS = 2 ± 1.7

Less ISRP with new formulation: 65 pat. (86.7%)
The same ISRP with both formulations: 7 pat. (9.3%)
More ISRP with new formulation: 3 pat. (4%)

CONCLUSIONS

- New adalimumab formulation was well tolerated and associated with less ISRP than the old formulation, therefore we expect better adherence, and persistence could also improve.
- We must develepo new studies to evaluate these aspects.