The therapeutic action of Dermune cream on dermatitis, lichen planus, and pustulous psoriasis

Materials and method

A study of the effectiveness of the new active principle was performed. A number of 134 patients were treated, 67 of them affected with dermatitis, 13 with lichen planus and 15 showing spam-plant pustulous psoriasis. The results were compared against the ones obtained from 39 control patients treated with the standard Clobetazol and Triamcinolona creams.

The cream containing the active principle (to be called from now on as the “Cream”) was prepared on hidrophile base. One type of the Cream was prepared at 36% and another at 50%. A Placebo was also made on hydrophilic base. All the cases were selected by personnel being unaware of the activities of the doctors and, in alternate way, they carried out biopsies to all the cases.

In general, the symptoms were classified in not improved, improved and cured. Checks of the differences of the results were performed for the use of the Placebo (applied on the controls) and the Cream. The square Chi test was employed for this purpose. Every patient was observed during one year to detect secondary effects.

As mentioned before, a few years long study was carried out. In this period various experiences were performed which are enumerated below:

**Experience 1.** A number of 18 dermatitis patients were treated using the Cream to 36%, by applying it 2 times a day, during 21 days. Another group of 10 cases were taken as controls applying on them the Clobetazol cream.

**Experience 2.** A number of 13 patients affected with lichen planus were treated with the 36% Cream and 9 were compared as control patients treated with Clobetazol cream. The same procedures were used.

**Experience 3.** A group of 13 patients showing psoriasis were treated with the Cream. The results are compared with the ones obtained of 12 patients to which Clobetazol was applied.

**Experience 4.** In this clinical experiment, the 36% Cream was applied to 15 patients affected with spam-plant pustulous psoriasis. Other 10 patients were treated with Triamcinolona cream. The same procedures were employed.

**Experience 5.** A group of 36 patients affected with dermatitis were treated. To one subgroup the Placebo was applied, to a second one, the 50% Cream was employed for the applications and in the last third subgroup the 35% Cream was used. The International PASI system was employed to determine the skin hurt percent witness in this experience. To perform it, a body map of each patient under these studies was made. All the studies were made double blind.
Experience 6. A study considering 45 patients of psoriasis was carried out by using three concentrations of the active principle: 0, 70 and 90%. As in the previous experience the method PASI was applied for processing the results.

Experience 7. The effect of the concentration was investigated in this experience. For this purpose the Cream to the 0%, 36% and 50% concentrations were applied to three groups, each of them of 15 patients. The PASI method was applied for the evaluation.

Experience 8. A study of relapses was done in a group of 24 patients suffering of dermatitis. Also, an analogous study with 23 patients affected of psoriasis was done. Both of the groups were treated at random with the Cream.

Results

Psoriasis knee before treatment and results after two months

In what follows the results obtained from each of the experiences enumerated in the past section will be presented in their consecutive order.


<table>
<thead>
<tr>
<th></th>
<th>Not improved</th>
<th>Improved</th>
<th>Cured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cream</td>
<td>0</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>3</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

The statistical difference between the results obtained by applying the Cream on a group of patients affected of dermatitis and Clobetazol on another control set of them, gave a significant: 96% of trust. Table 1 shows that a 100% of the treated cases improved with the application of the cream.
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Table 1. Shows the results for two groups of patients affected of dermatitis, under the application of the Cream and Clobetazol. Note that all the patients improved under action of the Cream.

Fig. 1 illustrates the results corresponding to the 18 cases of dermatitis treated: 100% of the patients were improved, and 44% of them were cured.

Fig. 1. Results of the application of the Cream in dermatitis patients: From 18 cases treated 100% were improved, and from them 44% were cured.

Next, Fig. 2 graphically shows the results of of experience in applying Clobetazol to the 10 control patients.

Fig. 2. Results of the application of Clobetazol to dermatitis patients. From 10 cases treated 70% were improved, and from these 20% were cured. The rest of the 30% patients were non improved.

Experience 2. Comparison of Cream vs. Clobetazol: lichen planus patients.

Table 2 illustrates the results associated to the treatment of lichen planus. Again the results with the use of the Cream are compared with the ones obtained from control patients to which Clobetazol was applied.

<table>
<thead>
<tr>
<th></th>
<th>Not improved</th>
<th>Improved</th>
<th>Cured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cream</td>
<td>1</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Control</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 2. The results of the comparison between the use of Cream in 9 patients of lichen planus and Clobetazol in a group 5 control patients also affected by this illness.

Note that the statistical difference of the results obtained with the Cream and wih the Clobetazol leads to
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a 88% of trust of the Cream against Clobetazol. The Table 2 also indicates that 88% of the treated cases were improved and of these 55% were cured. This result is graphically illustrated in Fig. 3.

![Fig. 3. Results of the application of Clobetazol in the control patients showing lichen planus: from the 88% of the improved cases 55% were cured.](image)

The Fig. 4 shows that from the 70% of the improved cases 20% were cured using Clobetazol.

It illustrates the superiority of the results obtained with the use of Cream with respect to the ones obtained by applying Clobetazol on the control patients.

![Fig. 4. Shows the results of the use of Clobetazol for treating lichen planus: from the 70% of improved cases 20% were cured.](image)

The results up this point, show a superiority of the healing action of the Cream with respect to the corresponding action of Clobetazol.

**Experience 3.** Comparison the Cream vs. Clobetazol: psoriasis patients.

The statistical difference of the results obtained from the application of the Cream in this experiences on psoriasis patients, is a significant 96% of trust in comparison with the results attained with the use of Clobetazol in the control cases. Table 3 shows that 100% of the treated cases improved with the use of the cream.

<table>
<thead>
<tr>
<th></th>
<th>Not Improved</th>
<th>Improved</th>
<th>Cured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cream</td>
<td>0</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>Control</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 3. Results of the use of the Cream and Clobetazol in patients affected by psoriasis.

The Fig. 5 depicts the results of the treatment of the 13 cases of psoriasis with the use of the Cream. The
30.8% of the cases were cured and the rest improved.

**Fig. 5.** Shows that of the 13 cases of psoriasis all were improved and of these 30.8% were cured. The statistical difference is the same as for dermatitis: 96% of trust.

**Fig. 6.** Illustrates that of 66% of cases of psoriasis improved with Clobetazol, 33% of them were cured.

**Experience 4.** Comparison of Cream vs. Triamcinolona: spam-plant pustulous psoriasis.

A study was carried out with 25 patients of spam-plant pustulous psoriasis. Along the 6 months during the experience, 15 of them were treated with the Cream and 10 using the cream Triamcinolona for the control cases. A 100% of the patients were cured with a statistical significance of 99.8% (See Fig. 7) with respect to the outcome in the control cases.

For the control experiment, it was obtained a 60% of improved patients, without achieving cures, as illustrated Fig. 8.

**Fig. 7.** Application of the Cream on spam-plant pustulous psoriasis: All the patients were cured. Cream was higher in statistical significance than Triamcinolona with a statistic significant of 99.8%. 
Fig. 8. There were 60% patients improved using Triamcinolona in the control patients. There weren’t patients cured.

Experience 5. Effect of the concentration: dermatitis patients.

It was carried out a study with 36 patients affected with dermatitis, using three concentrations of the active principle, 0%, 36% and 50. The PASI method was employed as a convenient mean to describe the percent of clearing of the lesions during 30 days. A bigger clearing was observed as the concentration of the active principle increases. The results are shown in Table 4.

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Patients</th>
<th>PASI %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>10</td>
<td>24.8</td>
</tr>
<tr>
<td>36%</td>
<td>12</td>
<td>77.3</td>
</tr>
<tr>
<td>50%</td>
<td>14</td>
<td>90.8</td>
</tr>
</tbody>
</table>

Table 4. Application of the Cream on dermatitis patients: the of clearing of lesions enhances by increasing the concentration of the active principle.


It was conducted a study with 45 patients in this case affected with psoriasis, using three concentrations of the active principle 0%, 36% and 50%. Again, the PASI method was used in order to appropriately describe the percent of clearing of the lesions during 30 days. A larger clearing was observed as the concentration of the active principle increases. Table 5 shows the results.

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Patients</th>
<th>PASI %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>36%</td>
<td>15</td>
<td>70</td>
</tr>
<tr>
<td>50%</td>
<td>15</td>
<td>90</td>
</tr>
</tbody>
</table>

Table 5. Effects of the concentration of the Cream on the results of applying it to psoriasis patients. Note the increase of the PASI index as the concentration grows.

Experience 7. Effect of the concentration and adverse reaction study.

During a period of 30 days, collateral effects were evaluated, such as atrophies of the skin, etc. The cases were treated with the Cream in the two available concentrations and Clobetazol. Statistically the zero value of 55% is appreciated with respect to the control, marking a large difference. The cream didn't
produced collateral effects in the patients. On the other hand Clobetazol produced them in a 33%. Table 6 illustrates the results.

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Without reactions</th>
<th>Atrophy bounce</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cream</td>
<td>40</td>
<td>40</td>
<td>No</td>
</tr>
<tr>
<td>Control</td>
<td>24</td>
<td>16</td>
<td>8</td>
</tr>
</tbody>
</table>

**Table 6. The comparative results of the study of collateral effects produced by the Cream and Clobetazol.**

Observe that the Cream did not produced collateral effects.

**Experience 8. Studies of relapses: dermatitis and psoriasis.**

Table 7 shows the results for 24 patients affected of dermatitis which were treated at random with the Cream. They were observed during a year following their clinical treatments, searching for relapses. Three relapses were observed for a 12.5%. Table 7 shows this outcome.

<table>
<thead>
<tr>
<th></th>
<th>Reactions</th>
<th>Without reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>3</td>
<td>21</td>
</tr>
</tbody>
</table>

**Table 7. The numbers of patients of dermatitis showing and not showing relapses in a one year period following the treatments with the Cream.**

As for the relapses in psoriasis cases, a group of **23** patients were chosen and treated at random with the Cream. They were observed during a year after their clinical treatment, searching for relapses. A number of 5 relapses were observed for a 21,7%. This results is larger than the corresponding one in the dermatitis case. The results are illustrated in Table 8.

<table>
<thead>
<tr>
<th></th>
<th>Reactions</th>
<th>Without reactions</th>
</tr>
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<tbody>
<tr>
<td>23</td>
<td>5</td>
<td>18</td>
</tr>
</tbody>
</table>

**Table 8. The numbers of patients of psoriasis showing and not showing relapses in a one year period following the treatments with the Cream.**

In concluding this section, it can be underlined that after comparing the results for three diseases studied, the highest statistic significance of confidence for the Cream corresponds to its application to spam-plant pustulous psoriasis patients.

**Discussion**
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The decision of starting the application of the considered active principle in the considered affections was motivated by the discovery that dogs affected of Dermatitis, very positively reacted to an active principle obtained from an inflammatory focus. Moreover, they also passively reacted to the application of parenteral and topical preparations of the active principle.

In this respect, it has been found by Murray\textsuperscript{5} that the inflammation is able to change the cells TH1 to TH2 and vice versa. Also, there exists the modern concept (Chouela\textsuperscript{6}) about that the psoriasis is a chronic inflammation where the lymphocyte T plays a fundamental role, even more intense in the pustulous kind of the illness. T

These concepts, suggested us an hypothesis about the possible mechanism of action of the active principle under consideration. Below we expose it. The cellular pattern of the considered type of illness, is illustrated in Fig. 9 for helping a further understanding, Pring\textsuperscript{7}.

![Cellular pattern type 1](image)

**Fig. 9.** Cellular pattern type 1.

Several therapeutic strategies exist to control these illnesses. One of them consists in to eliminate the action of the pro-inflammatory cytokines, using the proteins mergins, Krueger\textsuperscript{8}. Biological agents are also
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employed for lowering the number of lymphocytes, they eliminate the union of the lymphocyte with the CPA, Mehlis\(^9\).

Further, it can be underlined that the **immunologic deviation** is a therapeutic method provoking changes in the balance of the cytocins. For its implementation, the external cytocins IL4 had been employed. Below, the characteristic cellular pattern of the chronic eczema, an illness which symptoms are improved with the use of this cytocin, is illustrated.

**Fig. 10.** Cellular pattern type 2: chronic eczema.

Recently, another kind of immunologic response against the pathogens has been described, where the lymphocytes are activated in presence of a super-antigen, which is located in a place without having a relationship with the antigen. According to Kotsin\(^10\) et al, in the acute infectious diseases, the super-antigens are produced in enough quantities to be capable of inactivate a great quantity of lymphocytes. Fig.11 illustrates how the antigens stimulate 1 lymphocyte from a total number of 10,000.

**Fig. 11** Stimulus by outside antigens.

However the super-antigens stimulates a number of 3000, as it is shown in Fig. 12, Bonagura\(^11\).

According to this author, in a large quantity of cases of infectious illnesses, the balance goes toward the pathogen, due to the increase of the super-antigen.
The active principle described in this work is precisely obtained from an inflammatory focus. Therefore, according to Bottomly variations of the cells TH1 to TH2 should exist and vice versa. These alterations in these relevant immunologic cells in conjunction with the influence of the super-antigen can determine strong influences on the response of the system to the illness. In our view, the mentioned immunologic processes should be expected to be present in the mechanism of action of the active principle presented here. We expect to be able of investigating some of these questions in future extensions of the work.

Notes

* Pet Animals Clinic, “Jose L. Callejas”, Institute of Veterinary Medicine, Havana, Cuba.

** Biochemistry Department, Faculty of Biology, Havana University, Havana, Cuba.

*** Dermatology Department, “Guillermo Fernández Hdez. Baquero”, Specialized Hospital, Havana, Cuba.

**** Immunology Department, “Juan Manuel Marquez” Hospital, Havana, Cuba.

Bibliography


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