A CLINICAL COMPARISON OF BUDERSONIDE AND BECOTIDE NASAL\textsuperscript{R} IN PATIENTS WITH HAY FEVER. A SINGLE-BLIND STUDY.

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Summary

52 patients with seasonal allergic rhinitis were admitted to a randomized clinical comparison of budesonide (Rhinocort) and beclomethasone dipropionate (Becotide Nasal). All patients were sensitive to birch pollen, confirmed by skin-prick test. The drugs were administered intranasally 200\textmu g b.i.d.. Symptoms were assessed over four weeks starting with a run-in period of one week. Daily pollen counts were measured throughout the trial.

The patients' diary cards revealed a beneficial therapeutic effect of the two drugs. The pollen season was very mild this year and no statistically significant difference between the drugs was seen except for sneezing where Rhinocort showed less symptom. Side effects were few and transient for both drugs.

1981-11-16
Objective

To compare the efficacy and safety of budesonide and beclomethasone dipropionate (BDP) in patients sensitive to birch pollen allergen during the birch pollen season 1981.

Patients

52 out-patients, 30 males and 22 females, were admitted to the trial. Their ages ranged from 16-49 years (mean age 29.6 years). All patients had a history of hay fever (birch pollen allergy) with two or more of the symptoms blocked nose, running nose, sneezing and nasal itching for at least 2 years. All patients had been tested by skin prick test. All showed a positive reaction to birch pollen. Some of the patients were sensitive to grass as well.

Patient exclusion criteria

Pregnancy. Patients younger than 15 years of age. Patients with untreated fungal, bacterial or viral infections. Patients with a previous history of tuberculosis. Patients with nasal polyps causing obstruction.

Informed consent

Before including a patient into the trial the investigator gave full information about the trial and also about the right to withdraw, without prejudice, at any time. All patients gave their consent to participate in the trial.

Preparations and dosage

Budesonide (Rhinocort) and BDP (Becotide Nasal) were given as pressurized (freons) aerosols delivering 50µg active substance per puff. Both preparations were administered in 2 puffs into each nostril morning and evening providing the patient with a daily dose of 400µg active substance.
Batch number

Rhinocort DFB 20 B
Becotide Nasal OLR 559

Trial design

Single-blind, comparative study. Parallel groups.

Randomization

The coded preparations were administered in a randomized order by the nurse.

Duration of treatment

The trial started with a one-week baseline period followed by a three-week treatment period. All patients started on the same day, May 1, 1981.

Registration of symptoms

All patients were supplied with diary cards to record daily symptoms of blocked nose, running nose, sneezing, nasal itching and eye symptoms (running and itching) - severity being graded 0-3. 0 = no symptoms, 1 = mild symptoms, 2 = moderate symptoms and 3 = severe symptoms.

Before the start and at the end of the trial a complete physical ENT-examination was carried out. At the final visit to the clinic the physician as well as the patient made an overall assessment of the efficacy of the treatment.

Registration of side-effects

Side-effects were recorded daily in the diary cards.
Pollen counts

During the trial period (May 1-28, 1981) pollen was collected in a pollen trap for measurement of the daily birch pollen amounts.

Concomitant medication

No other medication against hay fever symptoms was allowed, with the exception of Antasten Privin® eye drops.

Statistical methods

Student's t-test was used for the statistical analysis of the symptom scores. $X^2$-test was used for the overall assessment.

Ethical committee

The trial was approved by the Ethical Committee of the Medical Faculty of the University of Gothenburg.

Results

51 patients completed the study. 26 received Rhinocort and 25 Becotide Nasal. One patient on Becotide Nasal did not return to the clinic. The trial was carried out during May 1981.

Figures 1-6 show the mean daily symptom scores for blocked nose, running nose, sneezing, nasal itching, total nasal symptoms and total eye symptoms. Symptoms presented during the trial were very low, and no statistically significant difference was seen between the two drugs, except for the sneezing score, which was significantly lower with Rhinocort during the period May 10-17th, when pollen counts reached the highest level. (Table 1).
Table 2 shows the overall assessment of the treatment efficacy made by the physician and by the patient. In 77% of the Rhinocort treated patients the clinical effects was assessed as very good by the doctor and in 73% by the patient. The corresponding numbers for Becotide Nasal were 56 and 60%. Chi²-test did not reveal any statistical difference.

Table 3 shows side-effects spontaneously reported in the diary cards. Side-effects were few and transient. One patient in the Becotide Nasal group and none in the Rhinocort group used eye drops.

Comments

The birch pollen season during this year (May, 1981) was rather mild which may explain the small difference between the drugs. Only the most sensible symptom, sneezing, was able to show a small but statistically significant difference between the drugs.
TABLE 1

Group mean symptom scores (±SEM) during Run-in (May 1-7th) (R1), treatment (May 8-28th) (T₁) and May 10-17th (T₂).

<table>
<thead>
<tr>
<th>Symptoms/Drugs</th>
<th>Nasal obstruction</th>
<th>Nasal secretion</th>
<th>Sneezing</th>
<th>Nasal itching</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R₁</td>
<td>T₁</td>
<td>T₂</td>
<td>R₁</td>
<td>T₁</td>
</tr>
<tr>
<td>Budesonide (B)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean</td>
<td>0.43</td>
<td>0.40</td>
<td>0.40</td>
<td>0.45</td>
<td>0.36</td>
</tr>
<tr>
<td>SEM</td>
<td>0.11</td>
<td>0.11</td>
<td>0.11</td>
<td>0.12</td>
<td>0.10</td>
</tr>
<tr>
<td>n=26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Becotide-Nasal (BN)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean</td>
<td>0.39</td>
<td>0.39</td>
<td>0.43</td>
<td>0.47</td>
<td>0.42</td>
</tr>
<tr>
<td>SEM</td>
<td>0.11</td>
<td>0.11</td>
<td>0.12</td>
<td>0.13</td>
<td>0.13</td>
</tr>
<tr>
<td>n=25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B - BN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean</td>
<td>0.04</td>
<td>0.01</td>
<td>-0.03</td>
<td>0.03</td>
<td>0.06</td>
</tr>
<tr>
<td>SEM</td>
<td>0.22</td>
<td>0.14</td>
<td>0.14</td>
<td>0.18</td>
<td>0.16</td>
</tr>
</tbody>
</table>

* p < 0.05
TABLE 2

Overall assessment of the treatment effect

<table>
<thead>
<tr>
<th></th>
<th>Rhinocort (%</th>
<th>Becotide Nasal (%</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Physician</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very good</td>
<td>20 (76.9)</td>
<td>14 (56.0)</td>
</tr>
<tr>
<td>Good</td>
<td>5 (19.2)</td>
<td>6 (24.0)</td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (3.8)</td>
<td>5 (20.0)</td>
</tr>
<tr>
<td>Slight</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>None</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>B. Patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very good</td>
<td>19 (73.1)</td>
<td>15 (60.0)</td>
</tr>
<tr>
<td>Good</td>
<td>6 (23.1)</td>
<td>5 (20.0)</td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (3.8)</td>
<td>5 (20.0)</td>
</tr>
<tr>
<td>Slight</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>None</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
TABLE 3

Side-effects

There were few side-effects in the two groups and they were mild and transient.

1. RHINOCORT
   One patient complained about "loss of voice".
   One patient complained about itching on the arms and legs.
   One patient complained about sneezing after spray.

2. BECOTIDE NASAL
   One patient complained about cough.
   One patient complained about swollen eyes.

Further four patients, 2 in each group, reported problem with the throat during the run-in period and during the treatment as well.

Eye drops (Antasten Privin) were used by one patient (Becotide Nasal).
NASAL ITCHING
MAY 1-7 RUN-IN, MAY 8-28 TREATMENT

SCORE

POLLEN

BECOTIDE N=25
RHINOCORT N=26
POLLEN

MAY
0 7 14 21 28
0 50 100
TOTAL NASAL SYMPTOMS
MAY 1-7 RUN-IN, MAY 8-28 TREATMENT
MAX POSSIBLE SCORE IS 12

- BECOTIDE N=25
- RHINOCORT N=26
- POLLEN

SCORE

POLLEN

MAY
TOTAL EYE SYMPTOMS
MAY 1-7 RUN-IN, MAY 8-28 TREATMENT
MAX POSSIBLE SCORE IS 6

SCORE

BECOTIDE N=24
RHINOCORT N=26
POLLEN

PIPKORN

POLLEN

MAY

0 7 14 21 28
0 50 100