Summary
Clinical Study Luffa comp. vs. Cromolyn sodium (DNCG) nasal spray

1. Design:

- multicentric (in 17 private practices)
- double-blind (neither doctor nor patient knows which test preparation (Luffa or DNCG) is being used by which patient)
- randomized (distribution of patients to treatment groups by chance)
- comparative (2 treatment groups, one receiving as test preparation Luffa comp. Heel nasal spray, the other 2% cromolyn sodium in identical, neutral packaging)
- controlled (the correctness of all raw data is being checked)

2. Methodology:
- 146 patients in Germany (upper Rhine Valley) suffering from seasonal allergic rhinitis (hayfever); performed during the hayfever seasons of 1996 and 1997
- the therapy lasted 42 +/-3 days and consisted of 4 x 1 (maximal 8 x 1) sprays into each nostril per day
- control examinations were performed at the beginning (day 1) and on days 7, 14, 28 and 42

3. Assessed parameters:

- The primary efficacy criterion was the overall score of the validated, hayfever-specific patient questionnaire, the RQLQ (RQLQ= Rhinoconjunctivitis Quality of Life). The RQLQ consists of 28 questions pertaining individual symptoms and was completed at every control examination.
- The secondary efficacy criteria were the descriptive (very good - not satisfactory) and the visual (100mm scale) assessment of the global efficacy by patients and doctors at the end of the treatment (day 42).
- Global tolerance was assessed by patients and doctors at the end of the treatment (day
  42).
- Furthermore, local tolerance (examined by rhinoscopy and patient rating), laboratory status, adverse events and quality of life were documented throughout the study.

4. Results:

- Both treatments showed therapeutic equivalence. This is demonstrated both by statistical analysis of the primary efficacy criterion (RQLQ overall score) and by the global assessment of efficacy (see fig. 1).

Statistics for comparative studies always start with the hypothesis that the tested medication (i.e. Luffa) is less efficient than the comparative medication (i.e. cromolyn sodium) because mathematics can only prove that something is wrong, not that it is correct. Analysis of this study showed that the hypothesis was wrong, Luffa is not less efficient than cromolyn sodium - which is the accepted proof

of equivalence for two treatments. (The difference between the treatments (Luffa has always a slightly lower score) as seen in the overall RQLQ score (see fig. 2) are not statistically significant.)

- Already during the first week of treatment, both treatments considerably reduced the patient's impairments (see fig. 2).

- Ongoing therapy resulted in steady improvement of symptoms (see fig. 2) and of quality of life (Luffa:+24% cromolyn sodium: +29% from day 1 to day 42).

- Both therapies were very well tolerated. This is documented by the results of the examinations as well as by the global assessment of tolerability (see fig. 3).

- There was no evidence of adverse systemic action for both therapies.

(normal values of laboratory and vital parameters; only 4 mild to moderate adverse events, which required no treatment)

5. Conclusion:

Luffa comp. nasal spray is a safe and effective alternative to conventional therapies against hayfever.

fig. 1:
Global assessment of efficacy

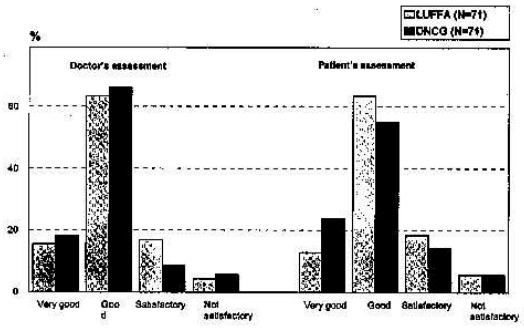


fig. 2:

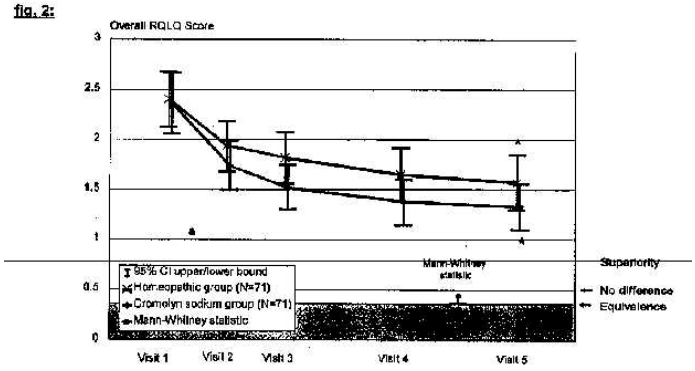
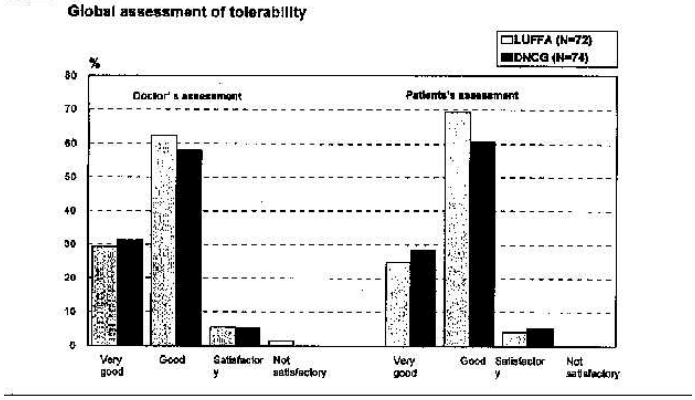

Overall RQLQ Score
3
2.5
2
1.5
1
0.5
0
95% CI upper/lower bound
Homeopathic group (N=71)
Cromolyn sodium group (N=71)
Mann-Whitney statistic
Mann-Whitney statistic
Superiority
No difference
Equivalence
Visit 1
Visit 2
Visit 3
Visit 4
Visit 5

fig. 3:


Global assessment of tolerability
LUFFA (N=72)
DNCG (N=74)
%
80
70
60
50
40
30
20
10
0
Doctor's assessment
Patients's assessment
Very good
Good
Satisfactory
Not satisfactory
Very good
Good
Satisfactory
Not satisfactory