DISTRIBUTION OF OPIATE REQUIREMENT IN PATIENTS ADMITTED TO TRAUMEEL® TRIAL* • OPIATE TREATMENT					
Group	**No**		**Yes**		
	No.	%	No.	%	Total
Treated	18	90.0	2	10.0	20
Untreated	4	57.1	3	42.9	7
Total	**22**	**100**	**5**	**100**	**27**

*Fisher Exact Test (2-tail), p=0.09

Tab. 5: Distribution of Opiate Requirement in Patients Admitted to Traumeel® Trial

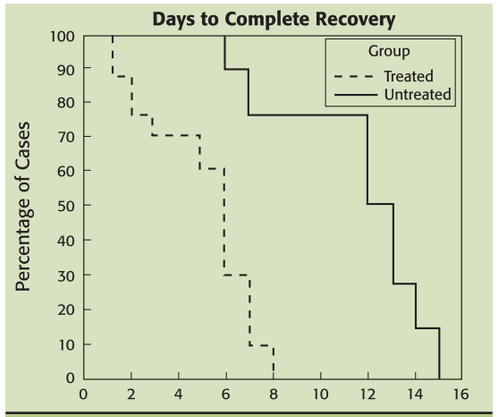
LIMITED CLINICAL TRIAL WITH TRAUMEEL® IN CHEMOTHERAPY-INDUCED STOMATITIS

We studied 27 subjects between the ages of 6 and 18 years to evaluate the feasibility of using Traumeel® Oral Liquid in Vials for treating chemotherapy-induced stomatitis. Twenty patients received Traumeel® and seven children who did not receive Traumeel® were chosen at random for a prospective follow-up to compare the duration of symptoms in study participants to untreated stomatitis patients. We assessed the distribution of ulcer severity in all participants according to WHO staging.

The age distribution (Table 2), stages of disease (Table 3), and anticancer treatments (Table 4) were similar in both groups. In the untreated group, however, opiate use was higher, although the difference was not statistically significant (see Table 5). All statistical analyses were carried out using BMDP Statistical Software.[13]

In all treated children, each treatment was followed by an immediate decrease in pain, which continued for 30 minutes to 2 1/2 hours. In children with Stages 1-2 stomatitis, the pain reduction lasted between 24-72 hours until the stomatitis disappeared. Children that began with Stages 3-4 stomatitis required 6-8 days of treatment. In two children with GVHD (graft versus host disease)-associated stomatitis, the pain was significantly reduced for several hours, and then 24 hours later the children ceased to complain about pain. Nevertheless, the basic process that had caused the stomatitis in these two children continued, so the children continued to receive treatment 2-3 times per day for another 5-10 days. Only one participant, a patient with Stage 4 stomatitis, according to the WHO definition, was receiving morphine at the beginning of the trial. Immediately after the first dose of Traumeel®, the morphine dosage was reduced by half. No other participant required treatment with narcotics, and those with Stages 1-2 stomatitis at the beginning of the trial no longer required analgesic treatment.

Table 6 shows the product-limit survival analysis that we used to compare symptom duration. From this table it can be seen that the difference between the two groups is highly significant, according to stringent statistical analysis. The median symptom duration in the treated group was 6 days, compared with 13 days in the untreated group.



Tab. 6: Days to Complete Recovery

CONCLUSION

We conducted this small preliminary study to gain a first impression about the effectiveness of Traumeel® Oral Liquid in Vials on mucositis. Obtaining positive results in such a study is a prerequisite to performing a large scale clinical trial according to strict scientific guidelines. Although we did not conduct this study as a randomized, double-blind trial, and the number of participants was small, the results were still impressive. Even if we presume that part of the success was due to the placebo effect, which is known to be very small in a hyper-acute system, such encouraging results led us to believe that Traumeel® Oral Liquid in Vials has genuine biological activity. In addition to its biological activity, the onset of action of Traumeel® was remarkable, with patients reporting a strong amelioration of pain within minutes. Some patients also reported a mood improvement. Such rapid action is unusual because the mucosa does not regenerate within minutes. Notably, the improvement persisted. Although the decreased use of opiates as analgesics in the Traumeel®-treated group was not significant, we recognized a clear tendency toward such a decrease, so we speculate that the results of a study on a larger group of participants might show a difference in favor of the Traumeel®-treated patients. The results of this limited, preliminary trial support the feasibility of performing a prospective, double-blind trial to assess whether positive results will be obtained under more stringent, scientific conditions, and whether Traumeel® treatment can reduce the duration of pain in stomatitis patients. Such a study is currently taking place in two medical centers in Israel.

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TREATMENT OF OTITIS MEDIA/EXTERNA WITH A MODERN HOMEOPATHIC REMEDY

Dr. Rainer Gottwald and Michael Weiser
Publication in preparation

Summary

The efficacy and tolerability of **TRAUMEEL EARDROPS/ OTEEL/BHI PURE EARDROPS*** was investigated in the treatment of 409 patients, suffering from otitis media or otitis externa. The preferred initially administered dosage of **OTEEL** was 3 monodose preparations daily (78%). Within a 5 day-treatment, 88% of the patients reported a significant improvement of their disease conditions. The total symptom score was reduced from 1.85 (baseline) to 0.35 (final visit). A success of the therapy, defined as a global investigator assessment of "very good", "good" or "satisfactory" was reported for 96% of the patients. The tolerability of the therapy was assessed as "very good" or "good" in at least 98% of the cases.

Otitis media, otitis externa, homeopathy, antihomotoxicology, cohort study, Oteel

* The name of this product varies internationally, but the formula remains the same. Alternatively, when this product is not available, the content of Traumeel ampules may be used for the same purpose.

GP, INT, Immu.

EUPHORBIUM COMP.

(CONTROLLED DOUBLE-BLIND STUDY OF A HOMEOPATHIC SINUSITIS MEDICATION)

Dr. M. Weiser and B.P.E. Clasen • Biological Therapy • Vol. XIII, No.1, 1995, pp. 4-11

Summary

Topic: Investigation of the clinical effectiveness of Euphorbium compositum S Nasal Spray in therapy of chronic sinusitis.

Design: Randomized, placebo controlled, double-blind study over a five-month period.

Subject / Collective: Included solely in this study were subjects who have suffered from established, chronically recurrent - although not acute - rhinosinusitis, for whom conservative therapy was indicated during symptom-free intervals. Excluded from this study, among others, were patients who smoked, suffered from nasoendoscopically confirmed polyposis or infectious rhinitis, who were known to possess unhealed apical granulomata, whose cases of sinusitis were established to be odontogenous, or who had undergone surgical treatment within the previous six months. The investigation encompassed a total of 172 patients, 155 of whom were included in the final evaluation (89.6%).

Intervention: 2 discharges of *verum* or placebo respectively into each nostril 4 times daily over a period of five months.

Chief Objective Variables: : For the purpose of statistical comparison among the therapeutic groups, a cumulative score was calculated from the data compiled in the three sectors "Subjective Symptoms ("day/night"), "Anterior Rhinoscopy", and "Ultrasound Examination of the Paranasal Sinus".

Results: Statistical comparison of the therapeutic collectives demonstrates significant superiority of Euphorbium compositum S Nasal Spray (5 % significance level, p = 0.016). Improvement was most evident within the subjective criteria of respiratory obstruction, sensation of pressure, and headache. Euphorbium compositum S Nasal Spray was well tolerated.

Conclusion: This study substantiates the reliable efficacy and good tolerance of Euphorbium compositum S Nasal Spray in therapy of chronic sinusitis. In addition, it demonstrates maintenance of a high standard of methods and acquirement of meaningful test results to indeed be feasible in homeopathy.

Euphorbium compositum S, chronic sinusitis, double-blind study

ENT, GP, DERM.