CLINICAL EVALUATION OF JADIT SOLUTION IN DERMATOMYCOSES

J. T. MARSHALL,* NAGAMANI MOHAN † AND P. BHAT †

Summary

A clincial evaluation of Jadit solution in 60 patients showed that there was 93.6% reduction in the mean severity scores of sign-symptoms on 21st day of treatment. 66.7% and 88.3% patients showed marked improvement on 7th and 21st day of treatment respectively. 91.2% patients showed absence of fungi on microscopic examination and 100% patients had a negative culture examination on 21st day of treatment.

The present study was undertaken with the primary objective of assessing the efficacy of Jadit solution of Hoechst Pharmaceuticals Limited. Jadit contains buclosamide which is chemically a 4-chloro-2-hydroxybenzoic acid N-butylamide. The composition of Jadit solution is given in the appendix.

Appendix :

COMPOSITION OF JADIT SOLUTION

Buclosamide	—	10%
Salicylic Acid I. P.	—	1%

Buclosamide possesses a broad spectrum of antimycotic activity on cutaneous fungi, like Microsporum, Trichophyton, Epidermophyton as well as several strains of candida, particularly Candida albicans.

Material and Methods

The trial was designed as an uncontrolled open study, in the outpatients attending the skin OPD of the affiliated hospitals of St. John's Medical College, Bangalore. Patients of either sex, having superficial fungal infection, involving less than 10% of the skin surface were selected for the study. Patients having secondary bacterial infection in the lesions were excluded from the study. Very severe cases having either of the following clinical features were also excluded :

1. Lesions covered with thick horny scales.
2. Lesions with marked local and inflammatory response, suggesting a localised hypersensitivity reaction to the infecting organisms.

Besides patients who had used any antifungal or keratolytic agent either locally or systemically within two weeks prior to the trial, were also not included in the present study.

The diagnostic criteria for entering the patient into the trial were clinical as well as laboratory. The patients showing a typical clinical picture of dermatomycosis in whom the microscopic examination of the scrapings using KOH mount showed the presence of fungal hyphae were finally selected for the trial.

* Department of Dermatology
† Department of Microbiology.
St. John's Medical College, Bangalore.

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The patients were admitted serially into the study. In order to minimize the drop out rate, only one bottle containing 10 ml. of Jadit solution was given to patients on every follow up, with instructions to apply the solution with the help of the applicator twice during the day and once at bed time. Strict instructions were given, not to wash the area of lesion or have a bath after application of the solution. The patients were also instructed not to apply the solution in the morning of the day of reporting to the OPD so that a drug-free scraping could be available for culture.

A careful record of any associated systemic disease was kept and thorough investigations were undertaken for detecting diabetes mellitus in presence of the least suspicion of the disease. Concurrent medication, like topical or systemic administration of antifungal agents, steroids, antibacterial or antihistamines as well as tranquillizers and sedatives was not permitted during the entire period of the study. Any medication other than the above mentioned, was kept to the bare minimum, only for unavoidable circumstances. A complete record of such concurrent treatment was kept. Any side effect, either observed during clinical examination or volunteered by the patients was recorded in full detail.

A clinical as well as laboratory evaluation was done before and on day 7, 14, and 21 of the treatment, as follows :

Clinical Evaluation :

A. Severity scores of +++ (severe), ++ (moderate), + (mild), 0 (absent) were given to five important sign - symptoms of dermatophytoses, namely, redness, burning, itching, scaling and vesicles.

B. An overall global assessment was given on the basis of the clinical status of the above signs and symptoms. It was expressed as either of the following :

(i) Complete disappearance of lesions.
(ii) Marked improvement.
(iii) Moderate improvement.
(iv) No improvement
(v) Worsening

Laboratory Evaluation :

A. Microscopic examination of the scrapings using KOH mount to demonstrate the presence of fungal hyphae was done before and on day 7, 14 and 21 of the treatment.

B. Culture examination using Sabouraud's agar medium containing 100 μgm of chloramphenicol per ml. was carried out before initiating the treatment and on 14th and/or 21st day of the follow up. Identification of the dermatophytes and candida was as described by Ajello (1966)[1].

Observations

A total number of 80 patients were included in the study. Twenty patients were lost to the follow up. Of the 60 patients available for analysis, 52 were males and 8 were females. The mean age of these patients was 29.4 ± 1.4 years. The mean duration of the disease was 2.42 ± 0.40 months. Table 1 gives the clinical and mycological diagnosis of these patients. Majority of the patients had Tinea cruris and the commonest fungus was Trichophyton rubrum.

Results of Clinical Evaluation

A. **Severity scores :** Table 2 gives mean severity scores of individual signs and symptoms on different days of follow up. It was seen that all these symptoms were almost equally affected by the treatment with Jadit solution.

TABLE 1
Clinical and Mycological Diagnosis of Patients

Clinical Diagnosis	No. of Patients	Mycological Diagnosis	No. of Patient
T. cruris	48	Trichophyton rubrum	22
T. corporis	3	T. rubrum and E. Floccosum	1
T. cruris et axillaris	1	E. Floccosum	9
T. corporis et axillaris	1	T. Mentagrophytes	2
T. cruris et corporis	4	Candida	7
Tinea (not specified)	3	Candida and E. Floccosum	2
Total	60	No growth	17
		Total	60

TABLE 2
Mean severity scores of individual signs and symptoms on different days of follow up.

Signs and symptoms	Day 0	Day 7	Day 14	Day 21
Redness (n=42)	1.14	0.33	0.12	0.10
Burning (n=28)	1.18	0.14	0.11	0.0
Itching (n=60)	2.13	1.05	0.65	0.10
Scaling (n=60)	1.70	0.95	0.47	0.18
Vesicles (n=16)	1.0	0.0	0.0	0.0
Total (n=60)	5.45	2.30	1.23	0.35

Figure 1 shows the percentage reduction in total severity scores during the follow up period.

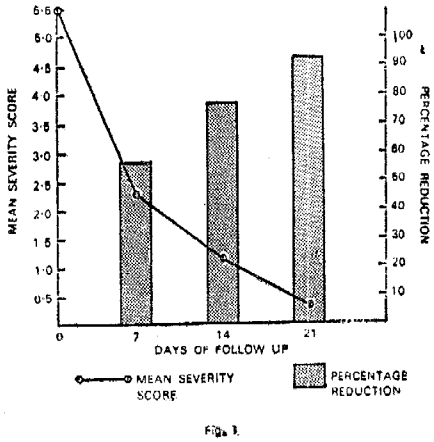

Fig. 1

Fig. 1 Mean severity scores and percentage reduction in severity scores on different days of follow up.

B. Global Assessment : 66.7% of patients had either complete disappearance of all the signs and symptoms or marked improvement on the first follow up day. By the last follow up day, 88.3% of the patients were either free from any sign-symptoms or at least they had marked improvement.

Results of Laboratory Evaluation

A. Microscopic examination to show presence of fungi

Of the total 60 cases available for analysis, 57 had a positive KOH mount showing the presence of fungal hyphae in the scrapings before starting the treatment. However, four patients out of 57 continued to have a Positive KOH mount whereas one patient had a negative KOH on 7th and 21st day and a positive KOH mount on 14th day of treatment. The response to treatment as revealed by the microscopic examination is shown in figure 2.

B. Culture Examination

Forty-two patients had positive and eighteen had negative culture prior to the commencement of therapy. Of these sixty patients, in twenty-

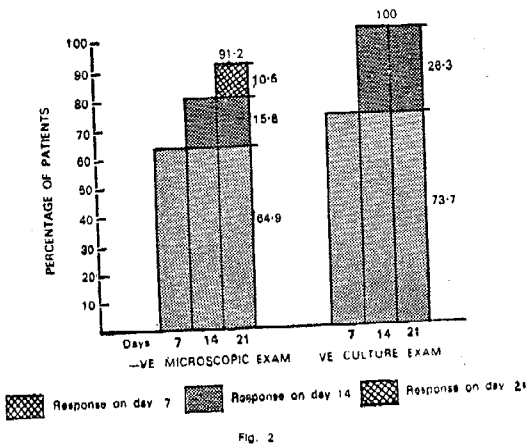

Fig. 2

Fig. 2 Percentage of patients showing a negative microscopic examination and a negative culture on different days of follow up.

two patients, healing of the lesions was so complete during follow up that no scrapings were available for culturing. In 31 patients, culture examination was done on one or more occasions during the follow up and results are as shown in Figure 2. In all these patients it remained negative on 21st day as well, showing the absence of any relapse. This data does not include those patients who had negative culture before the treatment was started, although all such patients remained negative during the entire period of treatment.

Combined data of Clinical and Laboratory Evaluation

Global and Microscopic Examination :

While combining the data of global and microscopic examination we have considered only those patients who had shown either complete disappearance or marked improvement of signs and symptoms on global assessment and at the same time had absence of fungi in microscopic examination. Table 3 shows the results. Figure 3 shows the percentage of these patients in different blocks according to when they first showed the response during follow up.

Out of the nine patients who did not show the response according to the above criteria, 4 patients had positive microscopic examination. However, it is noteworthy that out of these four, three patien's had complete disappearance of signs and symptoms, according to global assessment. Remaining five patients had a negative microscopic examination, but showed a moderate improvement in global assessment.

Global and Culture Examination :

As mentioned earlier, culture examination could not be undertaken in all patients on each follow up day. Twentyseven patients were examined on 7th day for culture, whereas 31 patients were examined on 14th day as well as 21st day of follow up. The results are shown in Table 3. Figure 3 shows the correlation between global and culture examination.

Global, Culture and Microscopic Examination :

Figure 3 shows a correlation between global, culture and microscopic examination. 71% of patients had a negative culture, absence of fungi on microscopic examination and marked improvement on global evaluation.

Side Effects :

Four patients out of eighty admitted to the study showed side effects and the treatment was discontinued within a week. Two of these patients had erythema and moderate vesiculations. One patient had burning and erythema, whereas one other patient complained of only burning.

Comments

In the present study it has been observed that Jadit solution has produced an excellent response. On 21st day of the treatment 88.3% of the patients had marked improvement, 85% had

TABLE 3

Number of patients showing either complete disappearance or marked improvement in signs and symptoms along with a negative microscopic and/or culture examination on different days of follow up.

Days of follow up	Number of patients showing response of		
	Global and micoscopic negative exam.	Global and negative culture exam.	Global, negative culture & negative microscopic exam.
Day 7	29/60	17/31*	12/31
Day 14	43/60	24/31	16/31
Day 21	51/60	26/31	22/31

*On day 7, out of 31, only 27 patients were examined for culture.

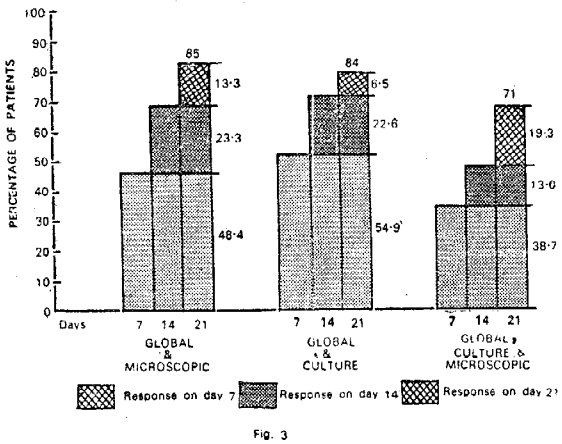

Fig. 3

Fig. 3 Percentage of patients showing a combined response of global assessment with microscopic, culture examination and the combination on all three.
Global: Either complete disappearance of signs and symptoms or marked improvement.

marked improvement as well as complete absence of fungus on microscopic examination and 84% patients had similar global assessment along with negative culture. 71% of patients had satisfied a strict criteria laid down by us wherein they had negative KOH as well as culture and at the same time either complete disappearance of sign-symptoms or marked improvement on global examination. In the rest of the patients there was at least moderate improvement. None of the patients showed absence of clinical improvement or worsening. A small number of patients had a negative culture and marked clinical improvement, but had shown presence of fungi on microscopic examination. Persistance of microscopic fungal elements even up to 90 days from a clinically healed and normal area is known to occur[2].

In the present study we had nine patients with candidiasis. It is interesting to note that in all these patients there was complete disappearance of signs and symptoms on the 21st day of treatment. All of them had negative culture and negative microscopic examination, except in one patient who had a positive KOH mount. In our opinion, Jadit solution has shown a very good response in patients with candidiasis. However, in view of the small number of patients, further work is required to collaborate our results in candidiasis.

The patient acceptance for Jadit solution was high, particularly because it is non-greasy and non-staining. It was well tolerated in all age groups. We did not observe any phototoxicity to Jadit solution in any of our patients.

Acknowledgement

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References :

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