Treatment of scabies with bis-butyl-carboethylene

F. ZORZI

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Background. **This study was designed to evaluate the efficacy of a bis-butyl-carboethylene preparation in eliminating the *Sarcoptes scabiei* mite in patients with scabies infection.**
Methods. **Twenty-two people with scabies (8 females, 14 males), aged from 8 months to 60 years, were treated with two applications of bis-butyl-carboethylene. After three days, the patients were re-examined and if the mite was still present further applications were prescribed. All patients were examined one month after the last application.**
Results. Sarcoptes scabiei **was eliminated in all 22 patients (100%): in 18 patients (81.8%) after one cycle of treatment (two applications), in two (9.1%) after another treatment and in two (9.1%) with two further treatments after the first cycle. The bis-butyl-carboethylene preparation was well tolerated by 20 patients (90.9%), and only two (9.1%) presented irritative eczema.**
Conclusions. **The bis-butyl-carboethylene oppears to be a useful tool in the therapy of scabies.**

KEY WORDS: *Sarcoptes scabiei* - Bis-butyl-carboethylene - Scabies drug therapy.

From the Institute of Dermatological Sciences, IRCCS, University of Milan, Ospedale Maggiore, Milan

The incidence of scabies in Italy and throughout Europe is continuously rising. The latest ISTAT figures (Italian Statistical Institute Year Book No.6 - Ed. 1993) indicate a total of 3000 cases reported in Italy. Although in Italy physicians are obliged to notify the authorities of the disease, it is widely believed that these figures are in fact an underestimate. There are increasingly frequent reports of real epidemics in hospitals and clinics, rest homes, drug detoxication centers, prisons, etc.[1,2]

Many reasons are suggested for this increase in the incidence of scabies. These include recent waves of immigration, "sex tourism" in the Third World, the severity and infectiousness of the disease in immunodepressed patients and HIV-positive subjects.[3] There is a spreading clinical impression that the sensitivity of the scabies mite has changed, making it more difficult nowadays to treat the disease.[4-6]

A product that has been on the Italian market since 1947 is based on bis-butyl-carboethylene combined with chlorobutanol and sulphoricinate soap. Bis-butyl-carboethylene is a maleic acid ester with two butanol molecules. Its acaricidal action is exerted directly through toxicity on the mite's vital centers. Chlorobutanol has an antimicrobial action, providing relief of itching. Sulphoricinate soap is a surfactant obtained by treating caster oil with sulphuric acid and serves to hold the active ingredient at the site of action, making it active against the mite eggs.

The product was authorized for sale under the trade name PAF® just after the Second World War and was widely employed. Demand dropped with the years, as the incidence of scabies declined.

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Address reprint requests to: F. Zorzi, Clinica Dermatologica, Via Pace 9, 20122 Milano, Italy.

TABLE I.—*Clinical features of patients with scabies treated with bis-butyl-carboethylene and results.*

Patient	Sex	Age (years or months)	Ethnic group	Duration of disease	Result after 1 cycle of treatment	Measures taken	Final check
D'A.R.	F	30	Caucasian	30-40 days	Eczema	Topical antibiotics and steroids	Recovered
B.C.	F	40	Caucasian	15-20 days	Improved		Recovered
M.F.	M	9	Caucasian	30 days	Improved		Recovered
M.A.	M	22	Caucasian	3 months	Improved		Recovered
S.P.	M	9 months	Caucasian	6 months	Scant improvement	Antiseptic bath, 2 other treatments and topical sulphur	Recovered
S.A.	M	3	Caucasian	4 months	Improved but not recovered	1 other treatment	Recovered
S.F.	F	30	Caucasian	3 months	Improved		Recovered
S.S.	M	20	Caucasian	3-4 months	Improved but not recovered	1 other treatment	Recovered
M.E.	F	32	Caucasian	2-3 months	Improved		Recovered
M.R.	M	8 months	Caucasian	2-3 months	Improved		Recovered
M.S.	M	30	Caucasian	2 months	Improved		Recovered
N.M.	M	38	Caucasian	2 months	Improved		Recovered
E.R.H.	M	2	Negroid	40 days	Improved		Recovered
E.R.A.	M	32	Negroid	20 days	Improved		Recovered
E.N.A.	F	24	Negroid	40 days	Improved		Recovered
D.P.W.	M	56	Caucasian	1 month	Improved		Recovered
I.C.	M	50	Caucasian	2 months	Improved		Recovered
C.M.	M	37	Caucasian	1 month	Improved		Recovered
Z.A.	F	60	Caucasian	3 months	Improved		Recovered
D'A.A.	M	22	Caucasian	30 days	Eczema, itching mite research +	2 other treatments+topical antibiotics and steroids	Recovered
C.S.	F	63	Caucasian	3 months	Improved		Recovered
N.V.	M	33	Caucasian	30-40 days	Improved		Recovered

With the recent flare-ups of the disease, bis-butyl-carboethylene has attracted fresh interest on account of its efficacy and safety, especially since mesulphene products have been withdrawn from the market.[7]

Materials and methods

In this open trial we treated 22 patients with scabies using bis-butyl-carboethylene (PAF® Laboratorio Farmaceutico Lofarma s.r.l.) with a view to verifying its efficacy and safety. The trial was not designed on a double-blind basis with a control group since this is an infectious, contagious, notifiable disease in Italy.

Patients were recruited on the following basis:

Criteria for inclusion.—Clinical picture typical of scabies; age 6 months-60 years, either sex; direct microscopic findings of the mite, its eggs or feces.

Criteria for exclusion.—Pregnancy or breast-feeding.

The preparation was to be diluted (one bottle in 150 ml water, for two applications) and applied to the skin of the whole body, from the neck to the feet, twice, with a 12-h interval. Three days later patients were re-examined (end of treatment, time T1).

Patients whose symptoms did not show remission at the T1 visit (relief of the itching), even if a direct search for the mite gave negative findings, received another treatment cycle, and were visited again after four days, i.e. one week after the initial therapy. Negative microscopic investigations for the mite were not considered proof of cure, since false negative findings are frequent, especially after recent treatment with scabicides.

All patients were seen again at a four-week follow-up visit. At this time patients were considered cured if they had no clinically suspicious lesions, and microscopic findings were negative. Patients with mild and diminishing residual itching, with papulo-nodular "post-infestation" residual lesions, and negative microscopic findings, were also considered cured.

Results

Table I shows the patients' main clinical features, the results of treatment, adverse reactions, and any measures taken. In total, one month from the first visit and subsequent treatment(s), all 22 patients (100%) were cured, 18 (81.1%) after the first treatment cycle, two (9.1%) after a second cycle, and two (9.1%) after two further cycles.

Safety

Two of the 22 patients (9.1%) complained of irritative eczema, or worsening of existing eczema, which was managed with antibiotics and steroids.

Discussion and conclusions

Bis-butyl-carboethylene was effective and well tolerated, curing all the patients (100%) in this trial; 90.9% tolerated therapy well, especially considering that all the other available treatments are irritant to varying degrees.

Generally a single treatment cycle was enough, although some patients in this trial needed a second or even third cycle. Only two patients (9.1%) complained of adverse reactions, which were mild and easily managed. The preparation was therefore simple and safe to use.

Particularly the shortness of treatment (two applications with a 12-h interval) ensures a very good compliance from the outpatient. When it is necessary its simple and quick use permits to treat, at the same time, all the family. It is well known that the failure of treatment or the relapsing of the disease is connected with a non contemporary family treatment.[8]

Compared to other drugs marketed in the United States and Europe, such as lindane, it does not have any risk of CNS toxicity.[9] Unlike benzyl-benzoate, which needs at least five or six days of topical application, bis-butyl-carboethylene is easy to handle, since clinical results are obtained in 24 h, and for patients who are not completely cured after one treatment cycle — as probably often happens, also with other therapeutic approaches — further cycles after three or four days did lead to full remission of the clinical picture.

In this study all patients, treated with one or more cycles of drug, recovered. These subjects were otherwise healthy, young, motivated and collaborative. They performed a linen and mattress decontamination by boiling and using of insecticide.[6]

Sometimes though, the patients with scabies are uncared and the failure of any treatment and the relapsing of the disease are due to the lack of hygienic measures because of their low social level of life.

To conclude, therefore, on account of its efficacy and safety, this preparation appears to be a useful tool in the therapy of scabies, which is still not easy to treat today.

Riassunto

Trattamento della scabbia con bis-butil-carboetilene.

Intoduzione. Scopo della studio è stato di valutare l'efficacia di una preparazione a base di bis-butil-carboetilene nella scabbia.

Metodi. Ventidue persone (8 femmine, 14 maschi) di età compresa fra 8 mesi e 60 anni affetti da scabbia sono stati trattati con due applicazioni di bis-butil-carboetilene.

Dopo 3 giorni i pazienti venivano esaminati e se l'acaro della scabbia era tuttora presente venivano prescritte altre applicazioni.

Tutti i pazienti sono stati esaminati dopo un mese dall'ultima applicazione.

Risultati e conclusioni. In tutti i pazienti è stata ottenuta la guarigione con eliminazione dell'acaro: in 18 pazienti (81,8%) dopo 1 solo trattamento (2 applicazioni), in 2 pazienti (9,1%) con un ulteriore trattamento e in 2 pazienti (9,1%) con 2 ulteriori trattamenti.

La preparazione di bis-butil-carboetilene è stata ben tollerata in 20 pazienti (90,9%), solo 2 pazienti (9,1%) hanno presentato un eczema irritativo.

PAROLE CHIAVE: Scabbia, terapia - Bis-butil-carboetilene - *Sarcoptes scabiei.*

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