Ivermectin versus benzyl benzoate applied once or twice to treat human scabies in Dakar, Senegal: a randomized controlled trial

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Objective To compare the effectiveness of oral ivermectin (IV) and two different modalities of topical benzyl benzoate (BB) for treating scabies in a community setting.

Methods The trial included patients aged 5–65 years with scabies who attended the dermatology department at the *Institut d'Hygiène Sociale* in Dakar, Senegal. The randomized, open trial considered three treatments: a single application of 12.5% BB over 24 hours (BB1 group), two applications of BB, each over 24 hours (BB2 group), and oral IV, 150–200 µg/kg (IV group). The primary endpoint was the disappearance of skin lesions and itching at day 14. If necessary, treatment was repeated and patients were evaluated until cured. Results were analysed on an intention-to-treat basis. A pre-planned intermediate analysis was carried out after the BB1, BB2 and IV groups had recruited 68, 48 and 65 patients, respectively.

Findings At day 14, 33 patients (68.8%) in the BB2 group were cured versus 37 (54.4%) in the BB1 group and 16 (24.6%) in the IV group ($P < 10^{-6}$). Bacterial superinfection occurred more often in the IV group than in the BB1 and BB2 groups combined (28% versus 7.8%, respectively; $P = 0.006$). At day 28, 46 patients (95.8%) in the BB2 group were cured versus 52 (76.5%) in the BB1 group and 28 (43.1%) in the IV group ($P < 10^{-5}$). These clear findings prompted early study cessation.

Conclusion Topical BB was clearly more effective than oral IV for treating scabies in a Senegalese community.

Une traduction en français de ce résumé figure à la fin de l'article. *Al final del artículo se facilita una traducción al español.* الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

Introduction

Scabies is a globally occurring ectoparasitic infection whose burden has been estimated to be as high as 300 million cases per year.[1] In developing countries, scabies is a significant public health problem because it is highly prevalent and complications are frequent. It is one of the main reasons for consultations in non-specialized primary health-care centres.[2] Children appear to be more commonly affected and are at a significant risk of streptococcal superinfection, which may be complicated by acute glomerulonephritis.[3] In addition, a recent study performed in the Gambia showed that skin lesions associated with scabies were the leading portal of entry for organisms that cause septicaemia in infants aged 3 months or less.[4]

Several topical treatments are effective: permethrin, lindane and benzyl benzoate (BB), with the last being considered the treatment of choice in most parts of Africa. On the other hand, oral ivermectin (IV) has also been shown to be effective, but the optimal number of courses is still a matter of some controversy. A recent meta-analysis[5] reported that, to date, there is no conclusive evidence that oral IV is superior to topical preparations for treating common scabies in the community setting.

We conducted a randomized controlled trial in Dakar, Senegal, to compare three modalities of treatment for scabies (i.e. oral IV and two forms of application of BB) with the aim of determining the most suitable treatment regimen in our setting.

Methods

Patients were included if they presented to the *Institut d'Hygiène Sociale* in Dakar, Senegal, and satisfied the following criteria: they were aged between 5 and 65 years; they were experiencing itching that involved at least three distinct sites on the body and had lesions that were characteristic of scabies (i.e. vesicles, papules, nodules or pustules) on at least three sites of predilection for scabies (i.e. the interdigital folds of the hands, the elbows, the wrists, the buttocks, the axillary folds, the nipple areolas in women and the male external genitalia), as assessed by a trained health-care worker;[6] and they were willing to participate in the study.

Patients were excluded if they satisfied any of the following exclusion criteria: there was doubt about the diagnosis of scabies; pruritus due to insect bites was present; the case patient or a member of his or her family had chickenpox; or the patient had been treated for scabies less than 1 month before the consultation; was under 5 years or over 65 years of age; weighed less than 15 kg; was pregnant or breastfeeding; was a women who used bleaching products for cosmetic purposes; had crusted scabies; had a general condition such as diabetes, high blood pressure or cardiovascular or neurological disease; or lived outside of the Dakar district. An HIV test was not required either before or after inclusion.

A parasitological examination was performed by low-power microscopy for each patient included in the trial. Skin scrapings were taken from each interdigital space in the hands and from the most clinically affected locations elsewhere.

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The scrapings were placed in a drop of 10% potassium hydroxide solution on a glass slide and examined for the presence of *Sarcoptes scabiei* (i.e. adult forms), eggs or faecal pellets. Negative findings on parasitological examination did not imply exclusion from the trial.

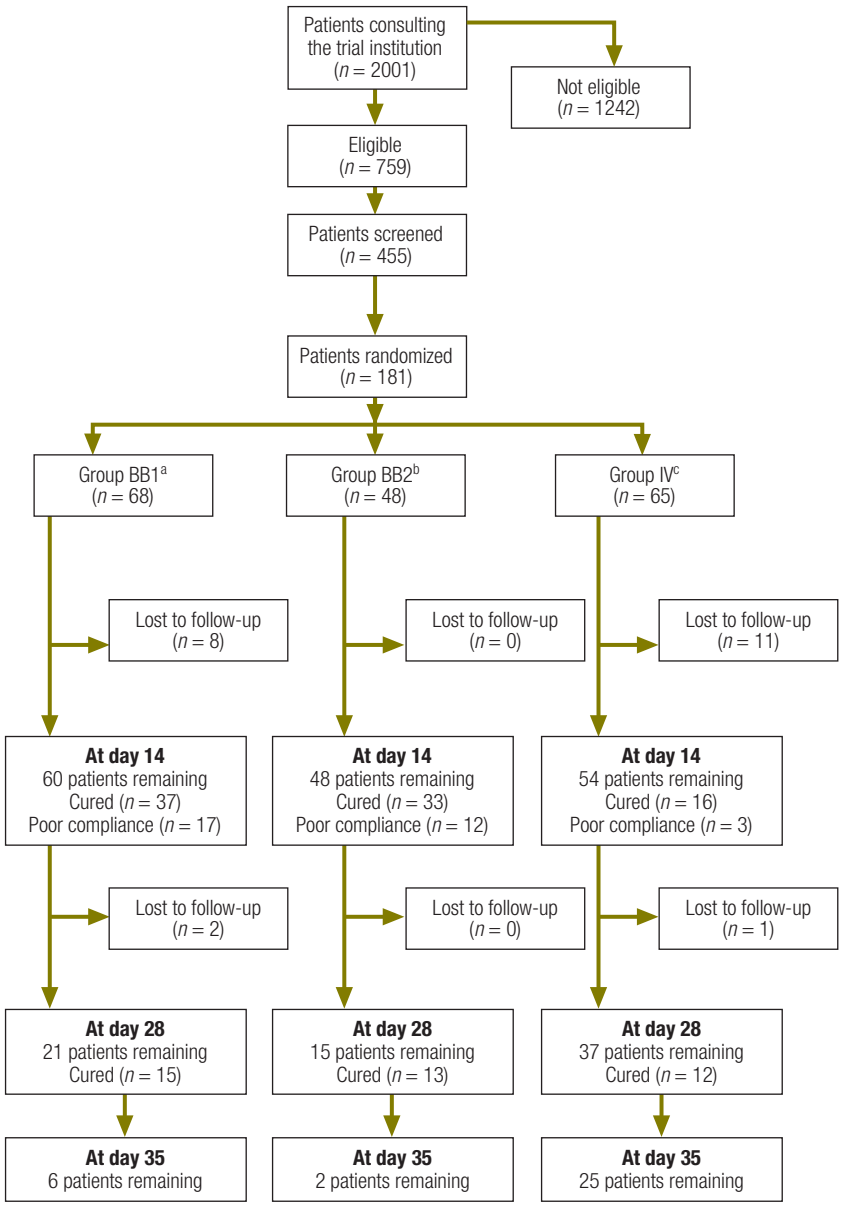
Setting

Senegal is a sub-Saharan country with 11 million inhabitants, and its capital, Dakar, has approximately 2 million inhabitants. The per capita gross national income is US$ 700. Forty per cent of the population lives in cities. The literacy rate is 50.4% in women and 72.8% in men. Fifty-seven per cent of the population is under 20 years of age.[7] The prevalence of HIV infection in the general adult population is estimated to be 0.8%.[8] Our unit is one of only two services that provide specialist dermatology care in Dakar.

Interventions

A randomized, controlled, non-blinded trial was carried out to compare three scabies treatments: a single oral dose of 150–200 µg/kg of IV taken on an empty stomach (IV group); one application of 12.5% BB, which was not removed for 24 hours, administered over the whole body except the head (BB1 group); and two such applications of 12.5% BB separated by 24 hours (BB2 group). To reproduce conditions found in the real world (i.e. a pragmatic trial), the investigators did not supervise compliance with any regimen. IV was manufactured by Merck, Sharp and Dohme-Chibret and was provided by the Senegalese national programme for controlling onchocerciasis. The expiry dates of the different drugs were checked.

Fig. 1. **Flowchart of a randomized trial comparing one or two applications of BB versus IV in the treatment of scabies, Dakar, Senegal**



BB, benzyl benzoate; IV, ivermectin.
[a] Group that received one application of benzyl benzoate.
[b] Group that received two applications of benzyl benzoate.
[c] Group that received ivermectin.

Randomization

A random number table was used to allocate treatment, with equilibration of asymmetries between the three treatment arms being carried out for every 40 patients. There was no provision for double-blinding. The study sample size was calculated based on the assumption that the difference in effectiveness between the treatment arms was less than 15%. The chosen significance level was 5%, and the power of the study was 80%. The total number of patients scheduled for inclusion was 400, distributed as follows: 150 in the IV group, 150 in the BB1 group and 100 in the BB2 group. Any member of a patient's family who was included in the trial received the same treatment as the index case.

At day 7, any patient who had clearly worsened was again given the same treatment as the week before. If at day 7 no change was noted or the patient had improved, nothing was done until day 14. If treatment failure was observed at day 14, the treatment first given was applied again. If treatment failure was noted at day 28, patients in either the IV or BB1 group were scheduled to be switched to two applications of BB, and those in the BB2 group were switched to IV.

Systematic cleaning of clothes and bedding was recommended. If a patient had a patent skin superinfection, an oral antibiotic (i.e. amoxicillin or erythromycin for 1 week) was given before randomization. Family members not included in the trial were given one

application of BB; namely, 493 family members of individuals in the BB1 group, 373 family members of those in the BB2 group, and 481 family members of those in the IV group.

The criterion for judging the effectiveness of treatment was the complete disappearance of visible lesions and itching at day 14. Also evaluated were treatment tolerability and compliance, which were assessed retrospectively by questioning the patients. Randomized patients were followed up every week until definitively cured (i.e. on days 7, 14, 21 and 28). The groups were also compared at day 28.

Statistics

The statistical analysis was performed using Stata 8.0 software (Stata Corp., College Station,TX, United States of America). Both an intention-to-treat and a per-protocol analysis were performed. The different treatment arms were compared using the χ^2 test. Odds ratios (ORs) were calculated, along with their 95% confidence intervals (CIs). We performed a multivariate analysis which took into account variables that differed by more than 20% between groups and variables that had a potential influence on treatment. The initial plan was to carry out an intermediate analysis using the Bonferroni adjustment when between 150 and 200 patients had been enrolled.

Ethical approval

The study was approved by the ethical committee of the Senegalese Ministry of Health and Prevention. A consent form was signed by all adult patients enrolled in the trial or by the parents of enrolled children. The document was translated into the local language if necessary. All treatments prescribed in connection with the study were provided free of charge, and a sum was allocated for patients' transportation to the study centre for follow-up visits.

Results

We present here the results of an intermediate analysis that was performed after 181 patients had been enrolled in the trial between July 2003 and September 2004: 65 in the IV group, 68 in the BB1 group and 48 in the BB2 group. The trial flowchart is shown in Fig. 1, and the demographic and clinical characteristics of the patient groups are summarized in Table 1.

Table 1. **Demographic and clinical characteristics of patients with scabies who received BB once or twice, or IV, Dakar, Senegal**

Characteristic	BB1[a] No. (%)	BB2[b] No. (%)	IV group[c] No. (%)	Total No. (%)	*P*-value
Age, in years					
≤ 15	47 (69.1)	23 (47.9)	40 (61.5)	110 (60.8)	0.07
> 15	21 (30.9)	25 (52.1)	25 (38.5)	71 (39.2)	
Sex					
Male	43 (63.2)	28 (58.3)	45 (69.2)	116 (64.1)	0.48
Female	25 (36.8)	20 (41.7)	20 (30.8)	65 (35.9)	
Disease duration,[d] in weeks					
≤ 2	17 (27)	13 (28.3)	11 (17.2)	41 (23.7)	0.25
> 2	46 (73)	33 (71.7)	53 (82.8)	132 (76.3)	
Superinfection before randomization					
Yes	24 (35.3)	11 (22.9)	19 (29.2)	54 (29.8)	0.35
No	44 (64.7)	37 (77.1)	46 (70.8)	127 (70.2)	
No. of sites involved					
≤ 5	41 (60.3)	30 (62.5)	31 (47.7)	102 (56.4)	0.20
≥ 6	27 (39.7)	18 (37.5)	34 (52.3)	79 (43.6)	
Parasitological examination result					
Positive	25 (36.8)	21 (43.7)	25 (38.5)	71 (39.2)	0.74
Negative	43 (63.2)	27 (56.3)	40 (61.5)	110 (60.8)	
Scabies in family members					
Yes	50 (73.5)	34 (70.8)	44 (67.7)	128 (70.7)	0.76
No	18 (26.5)	14 (29.2)	21 (32.3)	53 (29.3)	
No. of family members with scabies					
≤ 5	40 (59)	24 (50)	25 (38.5)	89 (49.2)	0.06
> 5	28 (41)	24 (50)	40 (61.5)	92 (50.8)	

BB, benzyl benzoate; IV, ivermectin.
[a] Group that received one application of benzyl benzoate.
[b] Group that received two applications of benzyl benzoate.
[c] Group that received ivermectin.
[d] Disease duration was unknown in some patients.

The male:female sex ratio was 1.78:1, the participants' mean age was 16.5 years (range: 5–63), and 110 of the 181 patients (60.8%) were aged under 15 years. The mean disease duration was 5.2 weeks (range: 1–20). Superinfection was noted in 54 patients (29.8%) before randomization. The number of sites affected was ≤ 5 in 102 patients (56.4%) and > 5 in the remainder. Overall, 128 index patients (70.7%) reported at least one other family member with scabies, and of these patients, 89% reported more than three family members affected. The parasitological examination result was positive in 71 patients (39.2%) and showed *Sarcoptes* in 63.4% of the cases, eggs in 33.8% and faecal pellets in 2.8%. There was no significant difference before treatment between the three groups in any of the following characteristics: age, sex, disease duration, number of sites involved, superinfection and number of family members with scabies (Table 1).

All eight patients who had clearly worsened clinically at day 7 were in the IV group; no patient who received BB required a second course of treatment at day 7.

By day 14, 19 patients were lost to follow-up: 8 in the BB1 group and 11 in the IV group. Three additional patients were lost to follow-up by day 28 (i.e. 2 in the BB1 group and 1 in the IV group). Failure to follow the treatment

protocol was noted in 32 patients: 29 applied BB either excessively or insufficiently and 3 took an inadequate dose of IV. Treatment compliance was significantly better in the IV group ($P = 0.002$). The use of adjunctive treatment measures was considered correct in 177 of the 181 patients (97.8%), and there was no difference between the treatment groups with respect to adjunctive measures ($P = 0.148$). The level of treatment compliance among all family members was 82%, and no difference was noted between treatment arms ($P = 0.7$).

Table 2 summarizes the study findings on the effectiveness of treatment. At day 14, 86 of the 181 patients (47.5%) were cured. The cure rate was higher in the BB2 group (68.8%) than in either the BB1 group (54.4%) or the IV group (24.6%), at a level of significance of $P < 10^{-6}$ overall. A comparison of the treatment groups showed that topical treatment (i.e. BB1 and BB2 groups combined) was superior to oral IV ($P < 10^{-5}$). Also at day 28, the cure rate was higher in the BB2 group (95.8%) and the BB1 group (76.5%) than in the IV group (43.1%), with $P < 10^{-5}$. An analysis of the subgroup of patients with parasitologically proven scabies showed that two applications of BB resulted in healing in 14 out of 21 patients (66.7%), one application, in 13 out of 25 (52.0%), and IV, in 7 out of 25 (28.0%), with $P = 0.029$.

Superinfection occurred during treatment in 27 of the 181 patients (15%): 18 of them were in the IV group, 5 in the BB1 group, and 4 in the BB2 group. The difference was statistically significant ($P = 0.006$).

Table 2. **Cure rates at treatment days 14 and 28 in patients with scabies who received BB once or twice, or IV, Dakar, Senegal**

Treatment	No.	Day 14		Day 28	
		Cured No. (%)	*P*-value	Cured No. (%)	*P*-value
BB1[a]	68	37 (54.4)	$< 10^{-6}$	52 (76.5)	$< 10^{-5}$
BB2[b]	48	33 (68.8)		46 (95.8)	
IV group[c]	65	16 (24.6)		28 (43.1)	
Total	**181**	**86**		**126**	

BB, benzyl benzoate; IV, ivermectin.
[a] Group that received one application of benzyl benzoate.
[b] Group that received two applications of benzyl benzoate.
[c] Group that received ivermectin.

We also performed a per-protocol analysis that excluded poorly compliant patients, those lost to follow up and those who had received less than 150 µg/kg of IV. The rates of healing observed were as follows: in the BB2 group, 84% at day 14 and 96% at day 28; in the BB1 group, 62% at day 14 and 91% at day 28; and in the IV group, 29% at day 14 and 50% at day 28. Topical treatment was still significantly better than oral IV ($\chi^2 = 24.3$, $P < 10^{-5}$).

Table 3 shows the results of a multivariate logistic analysis performed on the data collected at day 14, with the BB1 group serving as the control group. The analysis confirmed that the cure rate was highest in the BB2 group, followed by the BB1 group and then by the IV group. The OR for a cure in the BB2 group was 2.04 (95% CI: 0.89–4.66) and 0.23 (95% CI: 0.10–0.50) in the IV group (Table 3). Apart from the treatment type, only good compliance was significantly associated with a higher cure rate.

Table 3. **Results of multivariate logistic analysis of data collected 14 days after initiating treatment for scabies in randomized controlled trial, Dakar, Senegal**

Variable	OR[a]	95% CI
Two applications of BB[b]	2.04	0.89–4.66
Oral IV[b]	0.23	0.10–0.50
Age > 15 years	1.21	0.57–2.56
Parasitology test positive	1.04	0.52–2.08
Compliant with treatment	2.27	1.02–5.03
No. of sites initially involved ≥ 6	0.83	0.21–3.19
Superinfection before randomization	1.28	0.61–2.69
No. of family members with scabies > 5	0.70	0.43–1.16

BB, benzyl benzoate; CI, confidence interval; IV, ivermectin; OR, odds ratio.
[a] Ratio of the odds of achieving a cure.
[b] The reference group was composed of patients who received a single application of BB.

At day 28, the 25 patients in the IV group and the 6 in the BB1 group who were not lost to follow-up and who were not cured received two consecutive applications of BB, while the 2 patients in the BB2 group who were not cured were given IV. Two weeks later, all patients had been cured.

Treatment tolerance could be evaluated in 161 patients. Of these, 37 (23%) had minor adverse effects: irritant dermatitis in 18 patients in the BB2 group and 12 in the BB1 group, and gastrointestinal side effects in the IV group (abdominal pain in 5 patients and slight diarrhoea in 2). There was a statistically significant difference in the frequency of adverse effects ($P = 0.02$).

Given the clear difference in effectiveness between IV and both of the BB protocols and the significantly higher risk of superinfection during treatment in the IV group, the study was suspended for ethical reasons after the intermediate analysis.

Discussion

The study showed that topical BB was more effective for the treatment of scabies than oral IV, irrespective of the number of applications of BB. However, two applications of BB gave a higher cure rate at day 14 than one application. BB was so clearly superior and the rate of superinfection – a risk factor for post-streptococcal glomerulonephritis – was so much higher among patients on IV,[3,9] that we suspended the trial before its planned term. In multivariate analysis, only good compliance showed a statistically significant association with a cure.

Serological testing for HIV was not required, since the prevalence of HIV

Table 4. **Results of various therapeutic trials comparing oral IV with topical treatment for common scabies**

Ivermectin	Comparison drug	*n*	Cure rate (%) (IV vs comparison drug)	*P*-value	Lost to follow-up No. (%)	Reference
100 µg/kg once	10% BB for 12 hours	44	70 vs 48 at 1 month	0.08	0 (0)	[12]
200 µg/kg once or twice[a]	5% permethrin in single overnight application	85	70 vs 98 at 2 weeks 95 vs 100 at 4 weeks	0.0004 0.22	0 (0)	[13]
150–200 µg/kg once or twice[a]	1% lindane	53	74 vs 54 at 2 weeks 95 vs 96 at 4 weeks	0.19 0.99	10 (19)	[14]
200 µg/kg once	1% lindane	200	82 vs 44 at 4 weeks	$< 10^{-5}$	50 (25)	[15]
200 µg/kg once	10% BB	110	56 vs 51 at 3 weeks	0.69	30 (27)	[16]
200 µg/kg once	25% BB	58	93 vs 48 at 30 days	0.0002	Unknown	[17]
200 µg/kg once or twice[a]	25% BB daily for 3 consecutive days	210	79 vs 59 at 2 weeks 95 vs 86 at 4 weeks	0.003 0.04	10 (4)	[18]

BB, benzyl benzoate; IV, ivermectin.
[a] Two weeks after the first dose.

infection in Senegal is below 1%.[8] We assumed that most cases of scabies occurred in individuals without an HIV infection. Moreover, the presence of crusted scabies, which is suggestive of HIV infection, resulted in exclusion from the study. We also excluded patients who used skin bleaching products, a more commonly observed cause of skin immunosuppression in our context and a practice often accompanied by steroid use.[10]

We included in the study only patients whose diagnosis of scabies was certain in accordance with objective clinical criteria whose validity has been established in the same setting. The criteria were applied by trained observers,[6] and if any doubt about the diagnosis existed, the patient was excluded. Although the parasitological examination gave a positive result in only 39% of cases, a negative result did not preclude a diagnosis of scabies, since the sensitivity of this test is known to be less than 50%, according to previous studies.[11] The low rate of positivity we found may be explained by the high frequency (29%) of bacterial superinfection of the lesions. In any case, the effectiveness of treatment, whether IV or BB, was similar in parasitologically positive and negative patients. We chose to perform an open study rather than a double-blind study primarily for practical reasons but also because it is recommended in pragmatic trials. Patients lost to follow up and those who violated the treatment protocol were included in an intention-to-treat analysis. Patients who had clearly worsened at day 7 received a second course of treatment identical to that given the week before. However, it should be emphasized that only patients in the IV group received such treatment, which again provides evidence that IV is less effective. Finally, we had hypothesized a 15% difference in effectiveness between treatments, and we found a difference of 29%. The *a posteriori* power of our study to detect a difference between the BB2 group and the IV group was 96%.

Our results differ noticeably from the cure rates with IV and BB reported in the literature. Of seven randomized trials that compared topical scabicides to IV,[12–18] the four that compared IV and BB showed that IV was either an equivalent or a superior treatment (Table 4). We believe our results differ from those previously reported for several reasons. First, defined criteria for the diagnosis of scabies were applied in only four of the seven studies, and parasitological testing of scrapings was also performed in only four, which suggests that the diagnosis was unconfirmed in the others.

Second, although the proportion of patients lost to follow-up was at least 19% in three studies, the statistical analyses were performed under the assumption that the treatment was as effective in the patients lost to follow-up as in those who were observed at the study end-points, which is methodologically incorrect. In contrast, we used an intention-to-treat analysis.

Third, in four studies the single effectiveness end-point was assessed after 21–30 days, later than in our study. Surprisingly, the effectiveness of IV observed in our study appeared to be much higher at day 28 than at day 14, a result also seen in three other studies in which effectiveness was evaluated on two different dates. The only trial in which IV yielded a significantly higher cure rate than a topical treatment at day 14 was not randomized.[18] In addition, in that study a cure was defined as the "absence of pruritus and the absence of new lesions", whereas in our study the disappearance of clinical lesions was considered necessary. This suggests there may have been subjectivity in assessing the presence of a cure. In fact, we have no clear evidence that the use of a second dose of IV, as was given to some patients on day 7 or day 14 of our study, improved effectiveness. Had we continued to observe patients without giving them any additional treatment, the final effectiveness rate obtained with IV may have been higher. We did not choose this approach for ethical reasons, since the risk of superinfection made it essential to act as quickly as possible.

Fourth, 57.1% of the patients in our study had more than five affected sites and could thus be considered as having severe disease. It is possible that IV is more effective in milder cases of scabies, although the statistical analysis we performed did not provide any supporting evidence.

Fifth, the effectiveness of the topical treatments that were compared with

IV in previous studies appears to be unexpectedly low. Thus, it is possible that they were not used optimally. In our study, time was allocated to a thorough explanation of how BB should be applied. Moreover, our multivariate analysis yielded a significant association between good compliance and a cure.

Finally, there are possible pharmaceutical explanations for IV's relatively low effectiveness in our trial. It has been reported that *Sarcoptes scabiei* has developed at least partial resistance to IV,[19] and IV has previously been used for the mass treatment of onchocerciasis in Senegal.[20] In addition, some authors have suggested low effectiveness in children, who constituted the majority of our sample, because excretion of IV is reduced in subjects with a low physiological rate of sebum production.[21]

Conclusion

In our controlled trial, topical 12.5% BB was more effective and safer – particularly in light of the lesser risk of secondary superinfection – than oral IV for the treatment of common scabies in Dakar. Moreover, in developing countries like Senegal, economic considerations are important in the treatment of common disorders like scabies because there is often a need to treat large families. In our study, 51% of the patients had more than five affected family members. Since the difference in effectiveness obtained by applying BB once or twice was relatively modest, we recommend a single application rather than two as the standard first-line treatment for common scabies, with a second application prescribed only when there is treatment failure. The current cost of treating one person with scabies with a generic form of BB is approximately € 0.1 (less than 20 United States cents). ■

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Competing interests: None declared.

Résumé

Comparaison entre l'ivermectine et le benzoate de benzyle en une ou deux applications dans le traitement de la gale humaine à Dakar au Sénégal : essai contrôlé randomisé

Objectif Comparer l'efficacité de l'ivermectine par voie orale (IV) et du benzoate de benzyle (BB) administré par voie topique selon deux modalités pour traiter la gale dans un contexte communautaire.

Méthodes L'essai a porté sur des individus de 5 à 65 ans atteints de gale, qui s'étaient présentés au service de dermatologie de l'Institut d'Hygiène Sociale de Dakar au Sénégal. L'essai ouvert randomisé a comparé trois traitements : une application unique de BB à 12,5 % sur 24 heures (groupe BB1), deux applications de BB, chacune sur 24 heures (groupe BB2), et une prise d'IV par voie orale, à raison de 150-200 µg/kg (groupe IV). La principale mesure de résultat était la disparition des lésions cutanées et des démangeaisons au 14e jour. En cas de nécessité, le traitement était renouvelé et les patients étaient évalués jusqu'à ce qu'ils soient guéris. Les résultats ont été analysés en intention de traiter. Une analyse intermédiaire planifiée à l'avance a été effectuée après recrutement de 68, 48 et 65 patients dans les groupes BB1, BB2 et IV respectivement.

Résultats Au 14e jour, 33 patients (68,8 %) du groupe BB2 étaient guéris contre 37 (54,4 %) du groupe BB1 et 16 (24,6 %) du groupe IV ($p < 10^{-6}$). Les surinfections bactériennes étaient plus fréquentes dans le groupe IV que dans les groupes BB1 et BB2 pris collectivement (28 % contre 7,8 % respectivement, $p = 0,006$). Au 28e jour, 46 patients (95,8 %) du groupe BB2 étaient guéris contre 52 (76,5 %) du groupe BB1 et 28 (43,1 %) du groupe IV ($p < 10^{-5}$). Ces résultats clairs nous ont incités à interrompre précocement l'étude.

Conclusion Le benzoate de benzyle sous forme topique s'est révélé clairement plus efficace que l'ivermectine par voie orale pour le traitement de la gale dans une communauté sénégalaise.

Resumen

La ivermectina frente al benzoato de bencilo aplicado una o dos veces como tratamiento de la sarna humana en Dakar, Senegal: ensayo aleatorizado controlado

Objetivo Comparar la eficacia de la ivermectina (IV) oral y de dos posologías de benzoato de bencilo (BB) tópico como tratamientos de la sarna en un entorno comunitario.

Métodos El ensayo abarcó a pacientes de 5 a 65 años con sarna que acudieron al departamento de dermatología del Instituto de Higiene Social de Dakar, Senegal. Aleatorizado y abierto, este ensayo estudió el efecto de tres tratamientos: una aplicación única de BB al 12,5% durante 24 horas (grupo BB1), dos aplicaciones de BB, cada una de 24 horas (grupo BB2), y IV oral, 150–200 µg/kg (grupo IV). El criterio principal de valoración fue la desaparición de las lesiones cutáneas y el prurito al día 14. En caso necesario, se repetía el tratamiento y se evaluaba a los pacientes hasta que estuviesen curados. Los resultados se sometieron a análisis por la intención de tratar. Se llevó a cabo un análisis intermedio preplanificado en un momento en que los grupos BB1, BB2 y IV contaban con 68, 48 y 65 pacientes, respectivamente.

Resultados El día 14 se habían curado 33 pacientes (68,8%) en el grupo BB2 frente a 37 (54,4%) en el grupo BB1 y 16 (24,6%) en el grupo IV ($p < 10^{-6}$). Los casos de sobreinfección bacteriana fueron más frecuentes en el grupo IV que en los grupos BB1 y BB2 combinados (28% frente a 7,8%, respectivamente; $p = 0,006$). El día 28 se habían curado 46 pacientes (95,8%) del

grupo BB2, frente a 52 (76,5%) del grupo BB1 y 28 (43,1%) del grupo IV ($p < 10^{-5}$). La gran significación de estos resultados llevó a interrumpir el estudio antes de lo previsto.

Conclusión La aplicación tópica de BB fue claramente más eficaz que la IV oral como tratamiento de la sarna en una comunidad del Senegal.

ملخص

مقارنة الإيفيرمكتين بـبنزوات البنزيل المستخدم لمرة أو لمرتين لمعالجة الجرب لدى البشر في داكار، السنغال: تجربة معشاة مضبطة بالشواهد

الهدف: مقارنة فعَّالية إعطاء الإيفيرمكتين عن طريق الفم مع نمطين مختلفين من الاستخدام الموضعي لبنزوات البنزيل لمعالجة الجرب في مواقع مجتمعية.
الطريقة: شملت الدراسة مرضى تـتـراوح أعمارهم بين 5 و65 عاماً مصابين بالجرب ممن راجعوا قسم أمراض الجلد في معهد الصحة الاجتماعية في داكار، السنغال. وقد أخذت الدراسة المفتوحة المعشاة ثلاث معالجات في الاعتبار: استخدام لمرة واحدة لبنزوات البنزيل بتـركيز 12.5% على مدى 24 ساعة (المجموعة BB1)، واستخدام لمرتين لبنزوات البنزيل، كل منهما على مدى 24 ساعة (المجموعة BB2)، وإعطاء جرعة فموية من الإيفيرمكتين مقدارها 150 – 200 مكروغرام/كيلوغرام (مجموعة IV). وكانت النقطة النهائية الأولية هي اختفاء الأذيات الجلدية والحكة في اليوم الرابع عشر. وكانت المعالجة تعاد عند الحاجة ويعاد تقيـيم المريض حتى يشفى. وتم تحليل النتائج على أسس القصد للمعالجة. وأجرى الباحثون تحليلاً متوسطاً سابق التخطيط بعد بدء المجموعات الثلاث بالعمل وشملت 68 مريضاً لمجموعة BB1 و48 مريضاً لمجموعة BB2 و65 مريضاً لمجموعة IV.
الموجودات: في اليوم 14، شفي 33 مريضاً (68.8%) من مجموعة BB2 مقابل 37 مريضاً (54.4%) من مجموعة BB1 و16 مريضاً (24.6%) من مجموعة IV (قيمة الاحتمال P أقل من 10^{-6}). وقد حدث إنتان جرثومي إضافي لدى مجموعة IV (28%) أكثر مما حدث لدى المجموعتين BB1 و BB2 (7.8%) (وقيمة الاحتمال P 0.006) وفي اليوم 28 شفي 46 مريضاً في مجموعة BB2 (95.8%) مقابل 52 مريضاً في مجموعة BB1 (76.5%) و28 مريضاً في مجموعة IV (43.1%) (بقيمة احتمال أقل من 10^{-5}). وقد استوجبت هذه الموجودات الواضحة إيقاف الدراسة في وقت مبكر.
الاستنتاج: أثبت الاستخدام الموضعي لبنزوات البنزيل بوضوح أنه أكثر فعالية لمعالجة الجرب في المجتمع السنغالي، من الإيفيرمكتين.

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