Pilot study of the use of community volunteers to distribute azithromycin for trachoma control in Ghana

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Objective To assess the skills of community health volunteers in diagnosing active trachoma and distributing azithromycin in the Northern Region of Ghana.
Methods Six community health volunteers from Daboya were trained to diagnose trachoma and to treat the disease using azithromycin. They were also informed of the drug's possible side-effects. Under supervision, each volunteer then examined, and if necessary treated, 15 households. The dose of azithromycin was determined by weight; height was also measured. Tablets were given in preference to suspension when possible.
Results The volunteers' diagnostic sensitivity for active trachoma was 63%; their specificity was 96%. At the household level, their ''decision to treat'' was correct in 83% of households. In 344 treatment episodes, volunteers planned a dose of azithromycin outside the range 15–30 mg/kg on only seven occasions (2.0% of all planned treatments). The volunteers' drug management skills were good, the response of the community was excellent, and adverse reactions were infrequent. Diagnosis of active trachoma, record-keeping skills, and knowledge of side-effects were found to need greater emphasis in any future education programme. Most people aged four years or older were able to swallow tablets. For those taking tablets, the correlation between the data gathered for height and weight shows that calculating azithromycin doses by height is a valid alternative to calculating it by weight.
Conclusion Trained community health volunteers have a potential role in identifying active trachoma and distributing azithromycin. To simplify training and logistics, it may be better to base dosage schedules on height rather than weight for those taking tablets, which included most people aged four years or more in the population studied.

Keywords: trachoma, diagnosis, drug therapy; azithromycin, therapeutic use; community health aides, education; Ghana.

Mots clés: trachome, diagnostic, chimiothérapie; azithromycine, usage thérapeutique; auxiliaire santé publique, formation; Ghana.

Palabras clave: tracoma, diagnóstico, quimioterapia; azitromicina, uso terapéutico; auxiliares de salud comunitaria, educación; Ghana.

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Voir page 13 le résumé en français. En la página 14 figura un resumen en español.

Introduction

Trachoma is the world's leading cause of preventable blindness. Estimates suggest that 5.6 million people worldwide are already blind because of the disease, while another 146 million people may have active infection (*1*). The World Health Organization has recently adopted the "SAFE" strategy, with the aim of eliminating trachoma as a disease causing blindness by the year 2020 (*2*). The strategy is four-pronged: Surgical correction of trichiasis, Antibiotics for active trachoma, Face washing, and Environmental improvement (provision of latrines, control of flies, and related interventions).

With respect to antibiotic treatment, several studies have shown that a single or multiple dose of oral azithromycin is as effective in eliminating active trachoma as prolonged courses of tetracycline eye ointment (*3–6*). A randomized controlled trial comparing azithromycin with topical tetracycline given as a community-wide treatment for trachoma in the Gambia has revealed a favourable profile of side-effects for azithromycin (*7*). The main disadvantage of using azithromycin to control trachoma is its relatively high cost, which, at US$ 7–14 a dose, is too high for most countries where trachoma is endemic.

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Ghana has been chosen by the International Trachoma Initiative as one of five countries to receive a donation of azithromycin for the control of trachoma. To use this donation effectively it is necessary to determine how to distribute the drug safely and efficiently. There is an ongoing effort to eradicate guinea-worm disease in Ghana using volunteers from the community. A group of these volunteers from the Daboya subdistrict of the West Gonja district, Northern Region, has previously undergone training in the recognition of trachoma and its treatment with topical tetracycline. This report describes an operational study to assess the skills of community health (guinea-worm disease control) volunteers in diagnosing active trachoma, and to examine the feasibility of using them to distribute azithromycin for control of trachoma in Ghana. Additionally, to explore the logistics of azithromycin distribution, the proportion of children requiring tablets rather than suspension, as well as the correlation between height and weight in the treatable population, are analysed.

The objectives of the study were:

- to test the ability of community health volunteers to diagnose active trachoma accurately and to identify households requiring antibiotic treatment;
- to test the ability of community health volunteers to give the correct dose of azithromycin by weight to children and adults;
- to test the ability of community health volunteers to keep records of tablets received and distributed;
- to assess the incidence of possible adverse reactions to the azithromycin treatment delivered by the volunteers;
- to document the response of communities to trachoma diagnosis and antibiotic distribution being undertaken by the volunteers;
- to test the feasibility of giving azithromycin tablets to preschool children;
- to examine the relationship between height and weight in those requiring azithromycin for trachoma control.

Methods

Daboya is one of six subdistricts of the West Gonja district. In 1996, Daboya's 54 villages were estimated to accommodate some 28 714 people (*8*). Most live in traditional family compounds, surviving primarily by subsistence farming. The subdistrict is serviced by a single health clinic staffed by two medical assistants, a disease control officer, and a midwife. There are two ophthalmic nurses based in Damango Hospital, the main health care facility for the West Gonja district.

Six community health volunteers (five men and one woman) from Daboya were given training in the diagnosis of trachoma, in the SAFE strategy, and in the use of azithromycin (including the drug's side-effects). The education sessions extended over four days in late June 1999. The six volunteers had each participated in 7–18 days' training in trachoma before these four days, and were already working as "trachoma volunteers", distributing tetracycline eye ointment to people in their villages.

After training, each volunteer was asked to examine the members of 15 households in the presence of a supervisor (doctor or ophthalmic nurse). The volunteer was expected to examine both upper tarsal conjunctivae of all available members of the household who were aged one year or more. Handheld battery-powered monocular loupes were supplied. The supervisor examined all members of the household independently.

The volunteers were required to treat all members of any household in which there were one or more cases of active trachoma. Using the simplified trachoma grading scheme, these were designated as TF (the presence of trachoma follicles — "white dots") and TI (inflammatory trachoma causing obscuration of more than 50% of the deep tarsal blood vessels — "invisible blood pipelines")(*9*). When the volunteer and the supervisor had seen all members of a household, the volunteer was asked whether he or she felt that the household needed treatment. Where the volunteer and the supervisor disagreed, the supervisor looked at the volunteer's records and selected a patient or patients for re-examination.

In households needing treatment, community health volunteers were expected to weigh all subjects and to determine the appropriate dose of drug for each person, using tables that were supplied. Analogue scales that had been obtained locally were provided for volunteers. Supervisors independently recorded each individual's weight and calculated the appropriate drug dose. Additionally, to enable weight and height data to be compared at a later time, supervisors measured the height of each person in treatable households.

Azithromycin (Zithromax, Pfizer, New York) was given as a single oral dose of about 20 mg/kg, to a maximum of 1000 mg. Individuals weighing more than 10 kg were offered tablets. Children weighing less than 10 kg, and heavier children who were unable to take tablets, were given the drug in the form of a suspension. Pregnant women with active trachoma were treated with 1% tetracycline eye ointment twice daily for six weeks rather than with azithromycin. Pregnant women in treated households who did not themselves have active trachoma received no treatment. Where volunteers neglected to ask about pregnancy or determined an incorrect dose, they were stopped by the supervisor when the drug was about to be given to the patient. In this way they were given the maximum time to correct their own errors, so that the nature and rate of errors that might occur if the volunteers were unsupervised could be determined.

Before the start of fieldwork, each volunteer was given a defined quantity of azithromycin. When the volunteer completed examination of 15 households, he or she had to fill in an accounting form showing the number of tablets and number of

millilitres of suspension used in each household, to compare the quantities of drug used with the quantities returned, and explain any surplus or shortfall. Volunteers were able to refer only to their own records for this task.

Two to four days after receiving treatment, members of households were revisited by volunteers. Household members were questioned about symptoms since treatment, using open-ended questions ("Have you suffered any illness since you received the drug?") and specific questions about diarrhoea, nausea, vomiting, abdominal pain, itch, and rash.

Data were analysed using EpiInfo 6.04.

Results

Endemicity of active disease

A total of 675 householders were examined in 90 households. The supervisors identified 92 patients with active trachoma (TF and TI). The endemicity of active disease by age and sex is shown in Fig. 1.

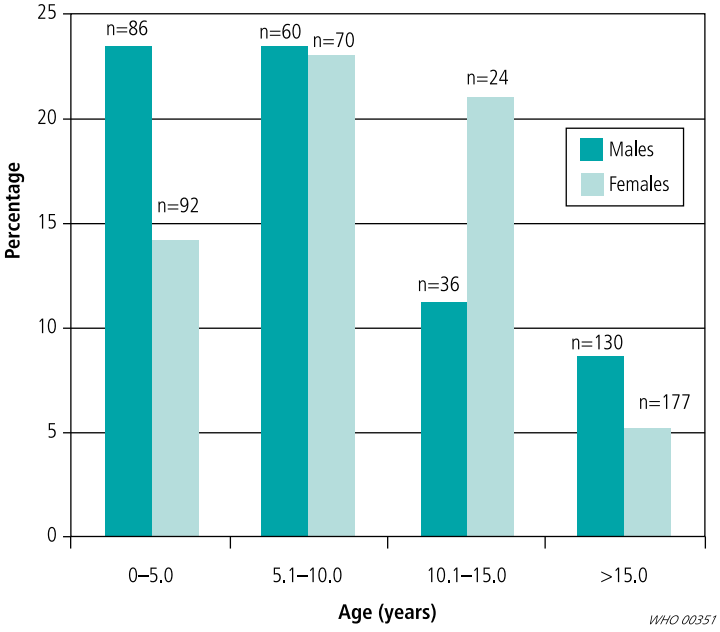
Ability to diagnose active trachoma

Thirty-four of 92 cases of active trachoma were missed by the volunteers. They also diagnosed TF and TI in 24 of 583 people who had no signs of active disease. Their diagnostic sensitivity was 63%; their specificity was 96%.

Azithromycin was distributed to all members of any household in which there was one or more cases of active trachoma. For operational purposes, in addition to the diagnostic reliability for individual patients, the decision of the volunteer to treat or not treat the entire household was of interest. The volunteers' "decision to treat" the household before discussion with the supervisor was correct in 75 of 90 households visited (83%; percentages for the six volunteers were 53, 87, 87, 87, 93 and 93).

Of the 15 incorrect decisions to treat, there were seven instances of planning no treatment for households in which treatment was needed, and eight of planning treatment where it was not needed. Collectively, these households contained 61 and 68 people respectively. In the seven "missed treatment" households there were 11 individuals with signs of active trachoma. If the one volunteer who had most trouble diagnosing active trachoma had been excluded from fieldwork, the decision to treat would have been incorrect for only eight households of 75.

Fig. 1. **Percentage of persons with active trachoma by age and sex**



Ability to give the correct dose

Of 90 households visited, 40 housed people with signs of active disease. The six volunteers collectively determined dosages for 344 individuals in these 40 households; 322 (93.6%) were correct. Four of the incorrect dose determinations consisted of offering the correct dose in the form of suspension to patients who were able to take tablets. Eleven errors out of 22 involved a minor dose error, with the planned dose lying in the range 15–30 mg/kg; three of these resulted from determining the weight of the patient incorrectly, the dose determined by the volunteer being correct for the weight they had recorded. In only four of 344 calculations for doses did the volunteers plan a dose that exceeded 30 mg/kg actual body weight. Only three planned doses were below 15 mg/kg body weight.

Ability to keep records of tablets received and distributed

Several volunteers found keeping records difficult. When children were unable to take the tablets offered, volunteers often forgot to record that suspension had been used instead. Similarly, when a tablet was refused but wasted in the process (for example, spat out), volunteers were sometimes seen to cross out the mark showing that a tablet had been given before recording the volume of suspension administered. This complicated their efforts to account for how the azithromycin had been used.

Of six volunteers, only two kept accurate records of tablets distributed and returned a balance of tablets that their paperwork showed to be the correct amount. Four of the six returned a volume of suspension within 5 ml of the calculated "correct" amount. Each of the volunteers managed the azithromycin carefully and returned all of the unused drug. Unfortunately, they were often not able to prove this from their own notes.

Adverse reactions

The concept of side-effects was a new one to most of the volunteers, and some had trouble remembering to warn households about the possible risks of azithromycin before offering the drug. When adverse events were reported at the follow-up visit, the volunteers had

difficulty distinguishing patients with persistent or potentially more serious events from those whose symptoms had abated or were abating. Thirty patients (22 males and 8 females) reported adverse events at follow-up (8.8%). Twenty-seven of these patients (or their parents) attributed symptoms to azithromycin, and three to malaria or other illness. By the time of the follow-up visit, only three of the 30 had continuing symptoms: an 8 year-old boy, whose pruritic red rash was gradually subsiding, and two men aged 35 and 40 who had persistent diarrhoea.

A summary of adverse effects encountered is presented in Table 1. Two treated individuals reported resolution or improvement of systemic symptoms after taking azithromycin: an 80-year-old man whose genitourinary symptoms resolved, and a two-year-old girl whose parents reported an improvement in pre-existing diarrhoea.

Community response

The study period coincided with the beginning of the wet season — a critical time to plant crops. Despite this, community response to the (often time-consuming) visits was almost always positive. Only one adult and six children (1% of eligible householders) refused to be examined.

One household of eight members, including one person who showed signs of active trachoma, refused treatment after being examined, weighed, and measured, on the grounds that it would further delay their departure to the fields. Three people from separate households left for farming duties while their families were receiving treatment and did not take the azithromycin that had been planned for them.

Using azithromycin tablets in preschool children

Of 341 treated patients, 294 (86.2%) were able to take tablets, and 47 (13.8%) took suspension. All treated individuals over six years of age took tablets. All those less than two years of age required suspension. The dosage form used for children between two and six years old is shown in Table 2.

The relation between height and weight

Data on height and weight were available for 355 people[a] in treatable households (households in which at least one case of active trachoma was identified). Fig. 2 presents a logarithmic plot of these data.

Using this log transformation, height cut-offs for doses of one, two, three, and four tablets are calculated as 83.4 cm, 102.3 cm, 124.5 cm, and 146.9cm.[b] People less than 83.4 cm tall would be assigned to receive suspension (zero tablets), those

Table 1. **Summary of reported side-effects (not all attributed to azithromycin)**

Symptom (No. of patients)	Duration (No. of days)			
	1	2	3	>3
Any illness	20	5	2	3
Fever	1	0	0	0
Diarrhoea	14	4	0	2
Vomiting	5	0	0	0
Abdominal pain	2	1	0	0
Dizziness	1	1	0	0
Weakness	0	1	1	0
Pruritus	2	1	1	1
Rash	0	0	0	1
Arthralgia	1	0	0	0

Table 2. **Form of azithromycin dosage used for treated individuals aged 2–6 years**

Age (years)	2	3	4	5	6
No. of individuals taking suspension (%)	18 (72)	7 (39)	5 (17)	2 (17)	1 (4)
No. of individuals taking tablets (%)	7 (28)	11 (61)	24 (83)	10 (83)	22 (96)
Total no. of individuals	**25**	**18**	**29**	**12**	**23**

83.4–102.3 cm would receive one tablet, and so on. The correlation between doses determined by weight and by height for all 355 people is shown in Table 3.

For those people whose weight and height readings were captured in this study, then, using the above height cut-offs to determine the number of tablets given results in the correct dosing of 296 of 355 cases (83.4%). Fifty-nine patients (16.6%) would have been overdosed or underdosed — none by more than one 250 mg tablet. Using height or length to predict doses of suspension for children was less reliable.

Discussion

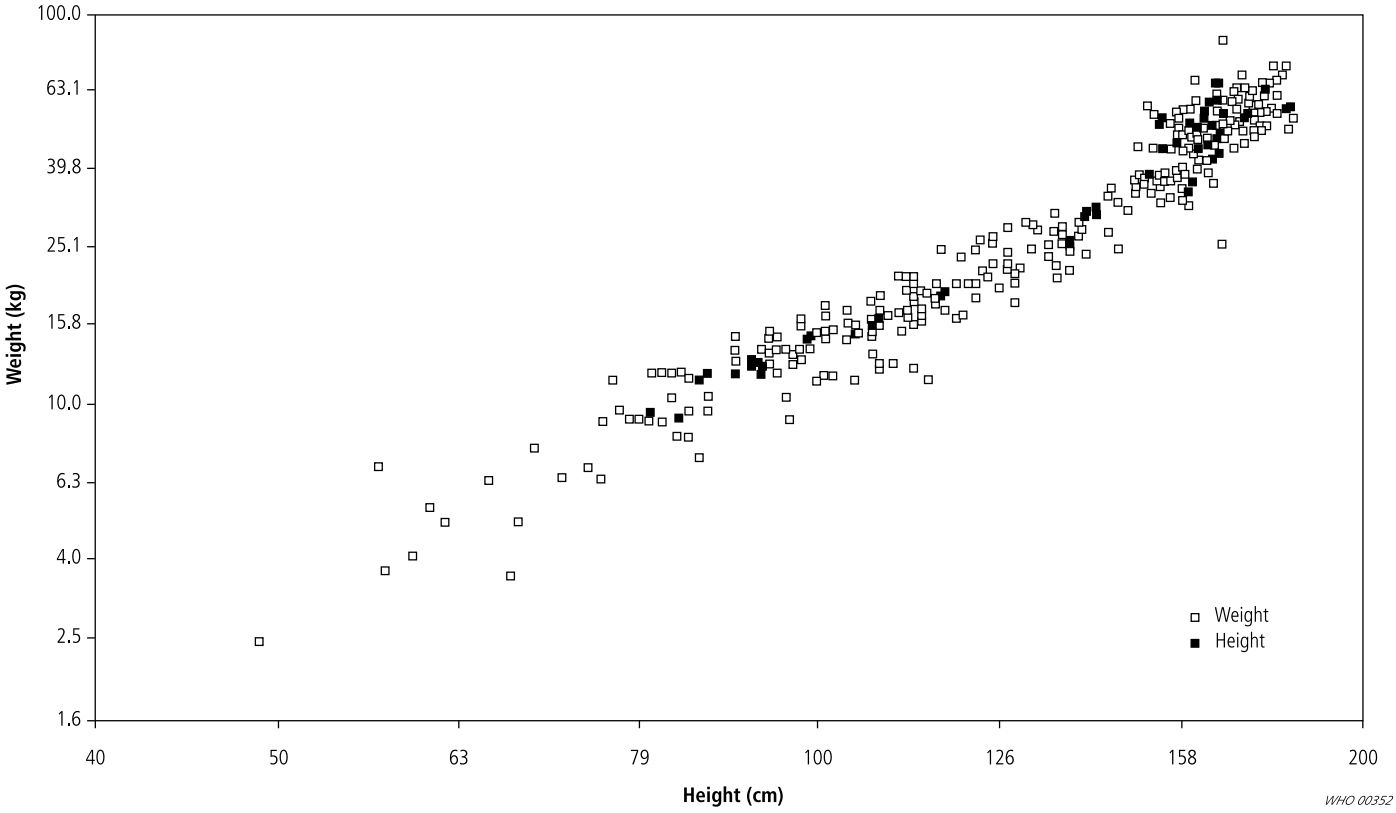
The recent commitment by the manufacturer to donate azithromycin to five countries with endemic trachoma provides the opportunity to reduce the prevalence of the infection dramatically, providing the drug is appropriately distributed to the community. The volunteers in this study all felt confident that the diagnosis of trachoma and distribution of azithromycin were tasks within their capabilities. The findings support that self-assessment, with several caveats.

Several elements of the study's design should be interpreted with caution. Our coverage of the communities visited was by no means complete. Often several members of the household, and occasionally whole compounds, were away farming at the time of our visit. The remaining individuals did not represent a random sample of the community, and our "endemicity" data therefore lack the

[a] This includes the 344 patients for whom doses were determined minus a 15-year-old paraplegic girl who could not be weighed but who did receive azithromycin, plus the eight members of the household that declined treatment after their weights and heights were measured, and four pregnant women. The supervisors' height and weight observations were used for analysis.

[b] The formula for derivation was $\log_{10}\text{wt} = 2.426(\log_{10}\text{ht}) - 3.66$.

Fig. 2. **Scatter plot of $\log_{10}$ (weight) v $\log_{10}$ (height)**



epidemiological validity needed for a label of trachoma "prevalence." Similarly, at the follow-up visits, it was unusual to be able to question each person who had received azithromycin. As a result, we were often forced to rely on the report of available family members on side-effects experienced by others in the compound. The analysis of the volunteers' ability to diagnose active trachoma assumes that the supervisors' assessments were correct in every instance. However, no mechanisms were put in place to validate their observations.

Working independently, the volunteers' "decision to treat" was correct in 83% of households. Diagnostic reliability on a subject-by-subject basis, however, was less impressive. In a setting with different prevalence of trachoma or household composition variables, the results for the "decision to treat the household" might not be so encouraging. On the other hand, if azithromycin was scheduled for community-wide distribution, diagnostic skills would not necessarily be required. In 344 treatment episodes, volunteers planned a dose of azithromycin outside the range 15–30 mg/kg on only seven occasions (2.0% of all planned treatments). Their drug management skills were good, and although their record-keeping skills were not, this probably reflects supervisors' assumptions that the task would be straightforward, with the resultant failure to emphasize record-keeping procedures during training. Community acceptance of the volunteers' role was high.

If further trials are attempted, a longer period of volunteer training is recommended. In hindsight, six rather than four days would have been more appropriate for the group of volunteers who took part in this study. For community health volunteers not previously given training in trachoma, three to four weeks' training might be needed.

During training, a greater emphasis on the clinical signs of TF, TI and TT (trichiasis — eyelashes touching the globe or evidence of epilation) is recommended. Teaching volunteers about TS (scarring of the tarsal conjunctiva — "white lines") and CO (corneal opacity) could probably be omitted. In the absence of other signs of trachoma, neither TS nor CO indicates the need for treatment or referral as part of the SAFE strategy, and presenting this

Table 3. **Number of individuals to receive doses of azithromycin (comparison of dosage calculated by weight and by height)**

Dose calculated by height	Dose calculated by height					
	0 tablet	1 tablet	2 tablets	3 tablets	4 tablets	Total
0 tablet	17	2	0	0	0	**19**
1 tablet	14	50	11	0	0	**75**
2 tablets	0	4	48	13	0	**65**
3 tablets	0	0	1	35	14	**50**
4 tablets	0	0	0	0	146	**146**
Total	**31**	**56**	**60**	**48**	**160**	**355**

material takes up time that could be used more effectively elsewhere. It is further recommended that instructions on how to record the use of azithromycin for both administered and wasted drugs be made more explicit in future education programmes. Practice at recording treatment scenarios likely to be encountered in the field (for example, a child requiring a second dose of tablets after spitting out the first) would be valuable. Similarly, more time needs to be spent on teaching volunteers about the side-effects of azithromycin and how to advise householders who are to receive the drug.

Most children aged four years or older were able to swallow Zithromax tablets. If this result were generally true of communities where trachoma is endemic, the task of distributing azithromycin would be made marginally easier. Particularly in remote communities, tablets are more readily transported, prepared, and administered than suspension.

Determining drug dosage by body weight proved to be problematic. The volunteers were initially unfamiliar with the technique for making a reading on an analogue scale, and found it difficult to calculate weight for small children who could not stand unsupported on the weighing platform. Ensuring that each of our volunteers was able to determine body weight reliably occupied a considerable proportion of the allotted training period. The scales themselves were bulky, and they performed poorly once dirt from the floors of compounds made its way into the mechanism. The good correlation between height and weight data for those people who needed treatment suggests that calculating azithromycin doses by height is a valid alternative for those taking tablets. In practice, the use of a folding measuring stick graduated in number of tablets rather than centimetres would be best, since it would eliminate the need for a conversion table. A spring scale with a hook and sling could be used to weigh children who needed the drug in the form of the suspension. If it were felt necessary to calculate doses by weight for all, the use of electronic scales would be preferable to analogue scales.

Conclusion

This study provides encouraging evidence that selected, trained community health volunteers may be able to diagnose active trachoma and distribute azithromycin for its control. Additionally, data from the small series of individuals treated as part of this study support the hypothesis that it may be possible to use height safely to determine azithromycin dosage for individuals taking tablets, including most people aged four years of age and above. Further work to evaluate the potential of these approaches seems justified. ■

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Résumé

Etude pilote sur le recours à des volontaires appartenant à la communauté pour la distribution d'azithromycine dans la lutte contre le trachome au Ghana

Objectif Evaluer l'aptitude de volontaires appartenant à la communauté à diagnostiquer le trachome actif et à effectuer la distribution d'azithromycine dans la Région Nord du Ghana.

Méthodes Six volontaires appartenant à la communauté de Daboya ont été formés au diagnostic du trachome et à son traitement par l'azithromycine. Ils ont également été informés des éventuels effets secondaires du médicament. Chaque volontaire a ensuite, sous surveillance, examiné et si nécessaire traité 15 ménages. La dose d'azithromycine était déterminée d'après le poids du malade, dont le volontaire mesurait également la taille. Si possible, le médicament était administré sous forme de comprimés plutôt que de suspension.

Résultats La sensibilité du diagnostic du trachome actif par les volontaires était de 63 %, et sa spécificité de 96 %. Au niveau des ménages, la « décision de traiter » était correcte dans 83 % des cas. Sur 344 épisodes de traitement, les volontaires n'ont prévu une dose d'azithromycine tombant en dehors de la gamme 15–30 mg/kg que dans 7 cas (2,0 % de l'ensemble des traitements prévus). Les compétences des volontaires en matière de gestion du médicament étaient bonnes, la réponse de la communauté excellente et les réactions indésirables rares. A l'avenir, les programmes pédagogiques devraient insister davantage sur le diagnostic de trachome actif, la tenue des dossiers et les effets secondaires. Dès l'âge de 4 ans, la plupart des malades sont capables d'avaler des comprimés. Lorsque l'azithromycine est administrée sous forme de comprimés, la corrélation entre les données rassemblées selon la taille ou selon le poids montre qu'il est tout aussi valable de calculer les doses en fonction de la taille qu'en fonction du poids.

Conclusion Après formation, des volontaires appartenant à la communauté peuvent jouer un rôle utile en identifiant les cas de trachome actif et en procédant à la distribution d'azithromycine. Pour simplifier la formation et la logistique, il pourrait être préférable de baser le calcul de la posologie sur la taille plutôt que sur le poids pour les malades prenant des comprimés, c'est-à-dire, si l'on se réfère à la population étudiée, la plupart des malades à partir de 4 ans.

Resumen

Estudio piloto del uso de voluntarios de la comunidad para distribuir azitromicina contra el tracoma en Ghana

Objetivo Evaluar las aptitudes de voluntarios de salud de la comunidad para diagnosticar el tracoma activo y distribuir azitromicina.

Métodos Se enseñó a seis voluntarios de salud de la comunidad de Daboya a diagnosticar el tracoma y a tratarlo con azitromicina. Se les informó también de los posibles efectos colaterales del medicamento. Tras esa capacitación, y siempre bajo supervisión, cada voluntario visitó y examinó 15 hogares, aplicando el tratamiento cuando lo consideró necesario. La dosis de azitromicina se determinó en función del peso; también se midió la talla. En la medida de lo posible se administraron comprimidos antes que la suspensión del medicamento.

Resultados La sensibilidad diagnóstica de los voluntarios para el tracoma activo fue del 63%; y su especificidad, del 96%. En los hogares, su «decisión de tratar» fue correcta en un 83% de los casos. De un total de 344 episodios de tratamiento, sólo en siete ocasiones (2,0% de todos los tratamientos previstos) los voluntarios calcularon una dosis de azitromicina no comprendida entre 15 y 30 mg/kg. Los voluntarios demostraron desenvolverse bien con los fármacos, la respuesta de la comunidad fue excelente, y las reacciones adversas fueron infrecuentes. Hubo que admitir que en el futuro los programas de educación habrían de hacer más hincapié en el diagnóstico del tracoma activo, en las aptitudes para la anotación de los datos y en el conocimiento de los efectos secundarios. La mayoría de las personas de cuatro o más años eran capaces de tragarse los comprimidos. Entre quienes utilizaron comprimidos, la correlación entre los datos referentes a la estatura y al peso muestra que el cálculo de las dosis de azitromicina en función de la talla es una alternativa válida al cálculo en función del peso.

Conclusión Los voluntarios de salud de la comunidad, debidamente capacitados, pueden ser una ayuda adicional para identificar el tracoma activo y distribuir azitromicina. A fin de simplificar la capacitación y la logística, conviene quizá basar las pautas de dosificación en la estatura en lugar del peso entre quienes tomen comprimidos, lo que significa la mayoría de las personas de cuatro o más años de edad en la población estudiada.

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