THE COMMUNITY-BASED TREATMENT OF ONCHOCERCIASIS IN SHAO, KWARA STATE, NIGERIA

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Abstract. Community acceptance of and compliance with annual ivermectin treatment in Shao, a sub-urban community in Kwara State, Nigeria, were remarkably high. Of 890 subjects from 204 randomly selected households, 832 (93.5%) had taken ivermectin at least once during the six-year treatment period. An average community acceptance rate (ACAR) of 88.77% (range 85.4 - 91.9%) was recorded during this period; a community compliance rate (CCR) of 74.76% was recorded. Overt refusals, covert refusals and those excluded from treatment were low and insignificant (p>0.05). The mean compliance age was 37.47 ± 16.52 years. Of the subjects studied, 40.67%reported adverse reactions to ivermectin during the first round of treatment (Tx1); this number decreased significantly (p< 0.05) to 15.43% during the sixth round of treatment (Tx6). Though considerable adverse reactions were reported in the community, these did not seem to have negatively affected acceptance of and compliance with annual ivermectin treatment; in some cases, the adverse reactions were believed by the villagers to demonstrate the efficacy and effectiveness of the drug. The community showed great awareness of the disease, its treatment with ivermectin and the distribution of the drug. On the basis of the high acceptance and compliance rates, it was concluded that Shao will benefit greatly from the current African Program for Onchocerciasis Control Strategy: Community-Directed Treatment with Ivermectin (CDTI) using Community-Directed Distributors (CDDs).

INTRODUCTION

Until recently, vector control using insecticide was the only available method of regulating onchocerciasis, a disease that causes visual impairment/blindness, skin disfigurement, lymphadenopathy, great socio-economic depravement and psycho-social stigmatization (WHO, 1995). Approximately 18 million people in Africa, Latin America and the Mediterranean Region, are affected; Africa alone accounts for over 90% of the global cases, with Nigeria being severely affected (WHO, 1995).

The introduction of a novel drug, ivermectin, which is a well tolerated microfilaricide for mass chemotherapy (in the absence of a suitable macrofilaricide), has revolutionized the control of onchocerciasis (Jenkins, 1990). Ivermectin acts on skin-dwelling microfilariae and as an *in-utero* microfilarial suppressant in the adult worm; its effects on transmission and on dermatological and ocular lesions are well documented (Dadzie, 1990; Alley *et al*, 1994; Boussinesq *et al*, 1995; 1997).

Ivermectin is given as a single oral dose annually or biannually in onchocerciasis endemic communities. The WHO (1995) reported that 1.5 million people were treated in Nigeria in 1993. With the active involvement of nongovernmental organizations (NGOs) in Ivermectin Delivery Programs (IDPs) in endemic communities, the number of people receiving treatment will continue to rise.

The results of outcome evaluations in communities that have received treatment for several years have not been widely reported in Nigeria; whereas outcome indicators are known to differ from one region to another (Collins *et al*, 1992; Baraka *et al*, 1995), the national picture is unclear. It is known that outcome is dependent upon a variety of factors

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including: the method of ivermectin distribution (Akpala *et al*, 1993); adverse reactions following treatment (Burnham, 1993); the adequacy of community mobilization and health education messages (Burnham, 1993; Baraka *et al*, 1995; Oyibo and Fagbenro-Beyioku, 1998); and general community participation. In our previous study (in preparation), it was shown that the prevalence of skin microfilariae (PMF), microfilarial density (MFD) and community microfilarial load (CMFL) depended on the level of community acceptance of and compliance with annual ivermectin treatment.

If control targets and objectives are to be reached, then healthcare providers need to understand the factors that often contribute to community acceptance and compliance. This study reports on the acceptance of and compliance with annual ivermectin treatment in Shao, Kwara State, Nigeria, where ivermectin has been distributed for a sixth time.

MATERIALS AND METHODS

Study area

This study was conducted in Shao, a semiurban community located north of Ilorin the administrative capital of Kwara State, Nigeria. The community of some 5,000 people, is made up of eight administrative units or divisions: Oke boo, Ogidiri,Oju -Oja, Oke Sinniga, Isale-Oja, Ode-Are, Oke-Lade and Ode-Alawon. Edungbola *et al* (1987) showed that this community was meso-endemic (54.6%) for the prevalence of the skin microfilariae of *Onchocerca volvulus*.

Mass ivermectin distribution

Mass ivermectin distribution began in 1990, using a clinic-based (basic health clinics) approach for the first round of treatment (Tx1). Subsequent ivermectin distribution (from 1991) was based on a house-to-house approach using community-based distributors (CBDs) who were supervised by a district health supervisor (DHS). A total of eight CBDs are involved in the annual distribution of ivermectin in Shao. At the time of this study, the commencement of the seventh round of annual ivermectin treatment was expected. Ivermectin is distributed in the community by the Africare Riverblindness Prevention Program, a non-governmental organization based in Ilorin.

Sampling methods

Eight hundred and ninety subjects from 204 randomly selected households (based on a cluster of households) from the eight divisions of the community were interviewed using structured questionnaires. In this study, *household* was defined as all people sleeping and eating in the same housing unit (Pacque *et al*, 1989).

Each subject was asked whether they had been taking ivermectin over the years. Rather than asking whether they took the drug during each year of treatment (Tx), that is in 1990, 1991, 1992, 1993, 1994 and 1995 (Tx1, Tx2, Tx3, Tx4, Tx5 and Tx6 respectively), they were simply asked to specify when they had not taken the drug; the respondents were therefore required to say precisely when ivermectin was not received rather than answering questions which required an affirmative answer. To ensure the correctness and the reliability of the responses, a collateral reporting technique was used: the CBDs, friends and relatives of the subjects were used as informants. Corroboration of responses by the informants reduced the vulnerability of the respondents to recall bias; the honesty and frankness of the villagers was not dubious as their answers corresponded with the treatment records kept by the ivermectin distributing agency. Owing to the annual mode of ivermectin distribution and the community awareness of onchocerciasis, it was relatively easy for the respondents to recall the events related to the drug and to its distribution. Results of an earlier study (in preparation) that related parasitological indices (eg the prevalence of skin microfilariae, microfilarial density and community microfilarial load) to the acceptance of and compliance with annual ivermectin treatment by using self-reporting over a four-year period

showed that recall bias, if it occurred, does not affect the general outcome of studies.

The subjects' responses regarding ivermectin treatment were recorded in the questionnaire using the following codes: A (Absence from treatment); T (Took ivermectin); O (Old age); R (Refused ivermectin treatment); L (Lactating mothers within three months of delivery) and S (Sick). In-depth interviews with key informants (CBDs; a schoolteacher; a nurse at the Basic Health Clinic) were conducted on an individual basis. The issues of perception of the disease and the treatment and distribution of ivermectin were discussed.

Data obtained were entered into a PC using the EPI INFO statistical package version 5.0. The outcome indicators (the community compliance rate [CCR]; the acceptance rate [AR]; the average community acceptance rate [ACAR] were computed as described in our previous study (Oyibo and Fagbenro-Beyioku, 1998).

RESULTS

A total of 890 subjects from 204 randomly selected households from Shao's eight divisions were studied. The mean age of the subjects' (years) \pm SD was 36.15 \pm 15.47 (range 12-69 years). Of the 890 subjects studied, 832 had taken ivermectin at least once representing 93.5% coverage of the sampled population.

Community ivermectin compliance

The calculated average community ivermectin acceptance rate (ACAR) for the 6year treatment period was 88.77%. The annual acceptance of ivermectin was variable: the highest was the sixth treatment round (Tx6=91.9%); the lowest was Tx4 (85.4%) (Table 1). The trend of the annual community ivermectin acceptance rate showed a decrease from Tx1 to Tx2 of 37.53%, followed by a leveling-off in Tx2 to Tx4 and an increase in Tx5 of 5.5%. The difference between annual ivermectin acceptance (Tx1-Tx6) was not significant (p>0.05).

Overt refusals to participate (expressed as a percentage of all those eligible who refused treatment) was low (<0.7%) in all the treatment rounds and was insignificant (p>0.05). Covert refusals, defined here as absence (A) during the time when treatment was offered. varied between treatment rounds. Tx3 and Tx4 had the highest rate of absenteeism (9.0%) each while the lowest rate was in Tx6 (5.4%). Comparisons between covert absentees and those that accepted ivermectin at Tx1-Tx6 was significant (p<0.05). Exclusion from treatment due to the contraindication of the drug was variable and low. Exclusion due to pregnancy ranged from 1.3-4.5% of the studied population during the treatment periods; lactating women (0.2-0.4%) and severely-ill persons not treated ranged from 0.2-0.7%. Generally, non-treatment due

Treatment period	Rate of ivermectin acceptance No. (%)	Subjects absent at treatment No. (%)	Severely-ill patients No. (%)	Patients that rejected ivermectin
Tx1 (1990)	806 (90.6)	64 (7.2)	0	0
Tx2 (1991)	776 (87.2)	74 (8.3)	6 (0.7)	6 (0.7)
Tx3 (1992)	778 (87.4)	0 (9.0)	2 (0.2)	6 (0.7)
Tx4 (1993)	760 (85.4)	80 (9.0)	4 (0.4)	4 (0.4)
Tx5 (1994)	802 (90.1)	56 (6.3)	2 (0.2)	4 (0.4)
Tx6 (1995)	818 (91.9)	48 (5.4)	6 (0.2)	6 (0.7)

Table 1 Ivermectin treatment data in Shao, Kwara State, Nigeria.

to contraindications (exclusion) varied between 2.0% and 5.0%.

Community compliance with annual ivermectin treatment from Tx1-Tx2

Of the 832 persons who had taken ivermectin at any of the treatment rounds, 622 took treatment during Tx1-Tx2, a community compliance rate (CCR) of 74.76%. The mean compliance age (years) \pm SD was 37.47 \pm 16.52. The community compliance with ivermectin differentiated by age groups was insignificant (p>0.05): all the age groups showed a similar tendency towards compliance.

Adverse reactions to ivermectin

Arthralgia, headache, itching, fever and dizziness were the adverse reactions that were reported. Two hundred and sixty-six (42.77%) of the 622 that complied had adverse reactions. In Tx6, only 96 (15.43%) of the complying group had any form of adverse reaction. The difference between adverse ivermectin rates in Tx1 (40.67%) and in Tx6 (15.43%) was significant (p<0.05; χ^2 =48.49; p-value=9.49; df=4). A 43.17% increase in subjects without adverse effects was recorded in Tx6 compared with the adverse rates in Tx1. A reduction in adverse ivermectin reactions among the subjects in Tx6 (62.97% reduction) was also recorded.

Though arthralgia occurred more often in both Tx1 (22.7%) and Tx6 (8.5%), no subject reported headache in Tx6. Those that presented with fever (12.12%) and arthralgia (22.7%) in Tx1 were fewer in Tx6 by 77.69% and 62.56% respectively. However, the number of subjects that presented with dizziness increased from 4 (0.4%) in Tx1 to 8 (0.8%) in Tx6.

In the compliant group, there was a 61.13% reduction in those that presented with arthralgia in Tx1 to 9.6% in Tx6. Similarly, those that complained of fever decreased from 12.2% in Tx1 to 3.2% in Tx6 (73.77%). It is worth noting that no subject reported dizziness in the compliant group in Tx6. Generally, only 25.2% of those with adverse reactions reported to a health official at any time.

Knowledge of onchocerciasis practices, ivermectin treatment and distribution

A high level of awareness of onchocerciasis, its treatment with ivermectin, and of the practices and information regarding the distribution of the drug was found. 96.2% of the studied population had heard of onchocerciasis; 86.5% of them knew that ivermectin is the current drug of choice for the treatment of onchocerciasis; 87.0% reported that they had been told that ivermectin was very good; 60.2% believed that ivermectin brought about good health; 85.8% believed that ivermectin could prevent blindness. However, 92.8% had not been told of the likely side reactions of the drug; 96% reported that they had been informed at the time of the next ivermectin dosing; 92.4% knew that ivermectin is taken annually; 92.6% knew that there were people excluded from treatment; 93.3% agreed to pay to cover cost of distribution. 84.3% of the studied population said that the avoidance of blindness was the motive for their continuing to take ivermectin

In-depth interviews revealed that the drug is generally well accepted. Instances of the drug's being used to treat intestinal helminths, to promote and restore fertility in barren women, to improve vision and sexual agility were narrated by the key informants, as were reports of adverse reactions that were supposed to be related to the drug's potency. Treatment with ivermectin was reported to have precipitated an asthmatic attack in a 52 year-old asthmatic woman on two occasions (Tx1 and Tx2); the patient had rejected subsequent treatment.

DISCUSSION

The pre-treatment endemicity level of 54.6% prevalence of microfilariae (Edungbola *et al*, 1987) qualified Shao for mass community-based ivermectin therapy, which began in 1990 in order to control onchocerciasis.

The acceptance of ivermectin by the community was considerable and was significant when compared with non-acceptance due to overt or covert refusal or exclusions from treatment due to contraindications. The average community acceptance rate of 88.77% (range 87.4-91.9%) was high although it varied (insignificantly) within the annual treatment periods. The coverage of 93.5% in the studied group was high and encouraging. Variations in the acceptance of ivermectin as a communitybased treatment have been reported from several countries. A 97% ivermectin acceptance was reported in Liberia (Pacque et al, 1989); coverage of 55.1-67.77% was claimed for the Onchocerciasis Control Program in West Africa (De Sole et al, 1989); 99.5% acceptance was found in the Sudan (Baraka et al, 1995). Other reports were given by Trpis et al (1990), Pacque et al (1991), Collins et al (1992), Boussinesq et al (1995; 1997), Chavasse et al (1995) and Rodriguez-Perez et al (1995).

We had previously achieved a positive treatment outcome with very high level of community acceptance and good compliance with an annual dose of ivermectin in a parasitological assessment of communities receiving ivermectin treatment in Kwara State (Oyibo and Fagbenro-Beyioku, 1997). A significant reduction in microfilarial load and prevalence was reported by Collins *et al* (1992) in Lose Andes, Guatemala, with an average acceptance of 93.78%. These studies underscore the importance of the constant monitoring of communities that receive ivermectin treatment.

The reasons reported in this study for the non-treatment of some patients differ from those of De Sole *et al* (1989) but reflected those of Pacque *et al* (1989). The number of those excluded from treatment due to contraindications or refusal/absenteeism was insignificant.

Though the annual acceptance of ivermectin in the treatment period ranged from 87.4% to 91.9%, the results of this study showed that only 622 (74.76%) of the 93.5% who were covered complied with annual ivermectin treatment. This finding differs significantly from the results of our earlier study in Patigi, Kwara State, where a community compliance rate of 1.9% was recorded (Oyibo and Fagbenro-Beyioku, 1998).

The 40.67% prevalence of adverse reactions to ivermectin in Tx1 was high compared with the 1.3% recorded in Liberia (Pacque et al, 1989), the 9% in the Onchocerciasis Control Program, West Africa (De Sole et al, 1989), the 13.1% in Eastern Nigeria (Chijioke and Okonkwo, 1992), the 14% in Central Togo (Heusckel et al, 1990), the 21.1% Sudan (Baraka et al, 1995), and the 29.5% in Guatemala (Collins et al, 1992); however the rate was favorable when compared with the 62.9% in Malawi (Burnham, 1993) and the 91.8% in Tanzania (Mwetta and Hills, 1994). The adverse events resolved spontaneously or were relieved by analgesics and/or antihistamines provided by the community health workers. Overall, ivermectin was safe and well tolerated by the community.

The 62.97% reduction in reports of adverse reactions following ivermectin treatment at Tx6 is remarkable. It agrees with reports that state that initial adverse reactions (referred to as Mazzotti reactions) are related to killing microfilariae *en masse*; these reactions are reported to subside following subsequent treatment (De Sole *et al*, 1989; Pacque *et al*, 1990; 1991; Burnham, 1993).

The high community acceptance of and compliance with annual ivermectin treatment recorded in this study warrant careful analyses. If compliance with therapy, as defined by Bond and Hussar (1991), implies a positive behavior by which a patient is sufficiently motivated to adhere to prescribed treatment because of the perceived benefits and likely outcomes, then the need to use a holistic paradigm when examining the factors that were at play in this community cannot be overemphasized.

The remarkable acceptance of and compliance with annual ivermectin treatment mirrored the willingness and readiness of the people to participate in therapy. The subjects demonstrated considerable knowledge of the disease, the treatment and the distribution. Information, education and communication strategy were effectively employed by the CBDs to relay health education messages to the people. During the interview process, the subjects referred to ivermectin as *ogun inarun* (a term in the Yoruba language that translates as drug for onchocerciasis). They identified ivermectin by its small size and by its annual distribution. The consequence of the community awareness was the generation of a strong demand for ivermectin, though the drug was distributed at the basic health clinic in Tx1. The ineffectiveness of health education messages in an earlier study (Oyibo and Fagbenro-Beyioku, 1998) was responsible for very poor acceptance of and compliance with annual ivermectin treatment among the people of Patigi.

A high rate of ivermectin reactions in Tx1 did not affect yearly acceptance: further evidence of the extent to which the people had been mobilized. In a study in Malawi, alarming adverse reactions in Tx1 (facial edema) brought about a reduction in the acceptance rate during the second round of treatment (Burnham, 1993); following adequate mobilization of the community with health education messages, the acceptance rate went up again. The exceptionally high acceptance of ivermectin in the Sudan was attributed to the involvement of local chiefs of the community, knowledge of onchocerciasis by the local residents and health education presentations. (Baraka et al, 1995). It is important to create a personalized, genuine and sustainable demand for ivermectin through health education (La Pin, 1992).

In-depth interviews with key informants were revealing and added to our understanding of the general acceptance of ivermectin within the community. The informants agreed that the de-worming effect of ivermectin on intestinal helminths brought about goodwill, which enhanced compliance. The belief that the drug promoted fertility was a factor: stories were told of two women who had been barren but who became pregnant after taking ivermectin. Claims of improved vision, better general health (alafia), and increased male sexual agility contributed to the positive local perception of ivermectin. Important also was the interpretation of adverse effects of ivermectin (itching, dizziness) as indicators of the potency of the drug. The transient nature of these adverse

reactions was taken to be a measure of the period of drug activity and subjects expressed displeasure at their not having had adverse reactions because they were keen to have a confirmation of the drug's efficacy.

The report of resumption of menstruation in three women with amenorrhea after treatment with ivermectin (Anosike and Abanobi, 1995) gave some credence to the local belief about ivermectin, which have enhanced compliance in no small way. The provocation of an asthmatic attack on asthmatic patients was also described by De Sole *et al* (1989), who asserted that ivermectin does not cause asthma *per se*. The mechanisms by which ivermectin may restore fertility and may provoke asthma are not known.

The proximity of Shao to the state capital, the social structures in place, the concentration of houses, and the presence of long standing missionary clinics contributed greatly to the awareness and dissemination of information in the community. The impact of the Community-Based Experience Service Center of the Department of Community Medicine and Epidemiology of the College of Medicine, University of Illorin is also worth mentioning: medical students and other health professionals in training (nurses and community health extension workers) undertake community health studies at most times of the year. The interaction of the members of the community with the trainees no doubt stimulates a general awareness of health issues.

Irrespective of the approach employed in ivermectin distribution in endemic communities, whether house-to-house or clinic-based, the need for the adequate mobilization of the people is crucial to proper disease control. The newlyestablished African Program for Onchocerciasis Control (APOC), a strategy of Community Directed Treatment using Community Directed Distributors (Dadzie, 1997), is based on empowering endemic communities to be in charge of their own treatment with ivermectin. This approach is laudable and ought to do very well. However, independent and continuous assessment of communities receiving annual ivermectin therapy using outcome indicators is mandatory. Feedback mechanisms, *ie* reporting between the communities and the control agencies (bi-directional reporting), will ensure that immediate intervention can be made when necessary to support compliance, strengthen the sustainability of Ivermectin Distribution Programs, and ensure the achievement of control objectives. The high acceptance of and compliance with annual ivermectin treatment reported in this study show that optimal settings for onchcerciasis control with ivermectin can be readily attained.

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