Baseline STD prevalence in a community intervention trial of the female condom in Kenya

P J Feldblum, M Kuyoh, M Omari, K A Ryan, J J Bwayo, M Welsh

Objective: We present baseline sexually transmitted disease (STD) prevalence rates from an ongoing intervention trial at Kenyan agricultural sites.

Methods: After gaining the cooperation of management, we identified six matched pairs of tea, coffee, and flower plantations and enrolled approximately 160 women at each site. Six intervention sites received an information programme and distributed female and male condoms, while six control sites received male condoms only and similar information about them. At clinic visits, we tested participants for cervical gonorrhoea (GC) and Chlamydia trachomatis (CT) by ligase chain reaction on urine specimens, and Trichomonas vaginalis (TV) by culture. The study has 80% power to detect a 10% prevalence difference during follow up, assuming a combined STD prevalence of 20%, 25% loss to follow up and intracluster correlation coefficient (ICC) of 0.03.

Results: Participants at intervention and control sites (total 1929) were similar at baseline. Mean age was 33 years, the majority were married, more than half currently used family planning, 78% had never used male condoms, and 9% reported more than one sexual partner in the 3 months before the study. Prevalences of GC, CT, and TV were 2.6%, 3.2%, and 20.4% respectively (23.9% overall), and were similar at intervention and control sites. The ICC for STD prevalence was 0.0011. Baseline STD was associated with unmarried status, non-use of family planning, alcohol use, and more than one recent sexual partner, but the highest odds ratio was 1.5.

Conclusions: Baseline results confirm a high prevalence of trichomoniasis and bacterial STD at these Kenyan rural sites. Improved STD management is urgently needed there. Our ongoing female condom intervention trial is feasible as designed. (Sex Transm Inf 2000;76:454–456)

Keywords: gonorrhoea; Trichomonas vaginalis; chlamydia; condoms; cluster randomisation

Introduction

The polyurethane female condom is approximately as effective as other barrier contraceptives. It is worn in the vagina, allowing the penis to move freely inside it, is compatible with oil or water based lubricants, but is more expensive than male latex condoms.

Epidemiological studies have reported lower sexually transmitted disease (STD) incidence in female condom users. Acceptability studies have had encouraging results, raising hopes that female condom availability may result in less unprotected intercourse. To date, however, studies have generally been small and short term.

We designed a large scale trial, employing a replicable intervention programme, to test the impact of female condom introduction on STD rates at agricultural units in Kenya. Here we report features of the cohort and baseline STD prevalence.

Methods

Full trial details appear elsewhere. We identified six matched pairs of tea, coffee, and flower plantations with primary healthcare clinics. One plantation within each pair (intervention site) received the female condom intervention programme relying on group meetings, puppetry and other folk media, lectures, printed materials, individual counselling, and female and male condoms. Control sites received a similar prevention programme, excluding female condoms.
Table 1 Features of study participants at intervention and control sites (%)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Intervention (n=960)</th>
<th>Control (n=960)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>11.0</td>
<td>9.5</td>
</tr>
<tr>
<td>25-29</td>
<td>22.9</td>
<td>25.5</td>
</tr>
<tr>
<td>30-34</td>
<td>21.3</td>
<td>22.8</td>
</tr>
<tr>
<td>35+</td>
<td>44.8</td>
<td>42.2</td>
</tr>
<tr>
<td>Highest educational attainment:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>27.3</td>
<td>26.1</td>
</tr>
<tr>
<td>Primary</td>
<td>63.0</td>
<td>60.1</td>
</tr>
<tr>
<td>Secondary</td>
<td>9.7</td>
<td>13.9</td>
</tr>
<tr>
<td>Marital status:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married, living with spouse</td>
<td>44.1</td>
<td>34.2</td>
</tr>
<tr>
<td>Married, not living with spouse</td>
<td>7.9</td>
<td>12.1</td>
</tr>
<tr>
<td>Married, polygamous</td>
<td>12.7</td>
<td>9.1</td>
</tr>
<tr>
<td>Unmarried, regular partner</td>
<td>28.0</td>
<td>37.3</td>
</tr>
<tr>
<td>Unmarried, no regular partner</td>
<td>7.3</td>
<td>7.4</td>
</tr>
<tr>
<td>Number of living children:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>4.7</td>
<td>5.5</td>
</tr>
<tr>
<td>1-3</td>
<td>47.3</td>
<td>45.8</td>
</tr>
<tr>
<td>4+</td>
<td>48.0</td>
<td>48.6</td>
</tr>
<tr>
<td>Current contraceptive method:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>42.0</td>
<td>40.9</td>
</tr>
<tr>
<td>Oral contraceptive</td>
<td>10.1</td>
<td>7.8</td>
</tr>
<tr>
<td>Injectable</td>
<td>36.3</td>
<td>40.2</td>
</tr>
<tr>
<td>Other</td>
<td>11.6</td>
<td>11.1</td>
</tr>
<tr>
<td>Ever use male condom</td>
<td>23.9</td>
<td>20.7</td>
</tr>
<tr>
<td>Currently use vaginal douche</td>
<td>23.6</td>
<td>21.1</td>
</tr>
<tr>
<td>Currently take alcoholic beverage</td>
<td>12.7</td>
<td>15.9</td>
</tr>
<tr>
<td>&gt;1 sex partner in past 3 months</td>
<td>8.6</td>
<td>8.8</td>
</tr>
<tr>
<td>No precautions to avoid STD</td>
<td>64.3</td>
<td>61.4</td>
</tr>
</tbody>
</table>

OUTCOMES

We diagnosed chlamydial and gonococcal infections by ligase chain reaction (LCx; Abbott Laboratories, Abbott Park, IL, USA) using urine specimens. We diagnosed vaginal trichomoniases with the InPouch TV test system (Biomed Diagnostics, San Jose, CA, USA) using self swabs. Specimens were shipped to the University of Nairobi department of medical microbiology within 24 hours, with urine specimens in cool boxes and InPouch cultures at ambient temperature. We used the odds ratio (OR) to calculate the association of baseline factors with prevalent STD.

Results

We screened 3031 women and enrolled 1929 (64%). About 17% of women approached had not been sexually active in the preceding 3 months, 16% were unwilling to participate, 11% were pregnant or desired pregnancy, and 3% were unwilling to answer questions about sex.

Women at intervention and control sites were similar (table 1): mean age 33.1 years, mostly married, with mean 3.6 living children. Women at intervention sites were more likely to be married and living with spouses. More than half the women used family planning, the most popular being the injectable hormone depot medroxyprogesterone acetate.

We queried participants about behaviours that may be associated with STD (table 1). Less than a quarter of the women reported ever using a male condom. Less than one in 10 women reported more than one sexual partner in the preceding 3 months. Most reported no special precautions taken to prevent STD, generally claiming mutual monogamy and no need for preventive measures.

Among 1922 women with STD data, the prevalences of gonorrhoea, chlamydia, and trichomoniases were 2.6%, 3.2%, and 20.4% respectively. Gonorrhoea prevalence was 2.0% at intervention and 3.3% at control sites; chlamydia prevalence was 3.1% and 3.2%; trichomoniases prevalence was 19.1% and 21.8% respectively. The combined STD prevalence, accounting for concurrent infections, was 23.9% overall, comprising 22.1% at intervention and 25.7% at control sites.

Site specific prevalences of gonorrhoea ranged from 1.3–6.1%; chlamydia ranged from 1.2–5.0%; and trichomoniases ranged from 10.6–29.9% (table 2). The lowest site specific STD prevalence was 13.4%, and the highest was 31.2%. The prevalence was higher at control sites in five of the six matched pairs, but the baseline intracluster correlation coefficient was 0.0011, indicating a minimal clustering effect.

In stratified analysis, unmarried women, non-users of family planning, women with more than one recent sexual partner, women with the least education, and current alcohol users all had elevated STD prevalence. None of these associations was strong, however (ORs from 1.2 to 1.5). STD prevalence was not associated with age, ever use of a male condom, or use in the past 3 months. Women who currently douchied had a lower prevalence (OR=0.7). When we included the above factors in a multiple logistic regression model, the ORs changed trivially.

Discussion

Urban cohorts in Kenya have higher rates of cervical infection than in this study. STD data from rural Kenya are scant. In one primary healthcare centre, the prevalences of gonorrhoea, chlamydia, and trichomoniases were 3.8%, 6.3%, and 10.9% respectively. Our study documents high STD prevalence in a large rural cohort, although plantations are not representative of rural areas generally.

Less than one quarter of study participants had ever used a male condom. Male condoms have been freely available for years at the plantation clinics, through outreach, and in dispensers at common areas. But the outreach workers did not receive regular training or time off for motivation activities; some of the...
condom dispensers were found to be empty at study initiation visits; and STD prevention was not a clear management priority and had withered. Effective means of reaching men and inducing more consistent condom use is an urgent need, as is sharper motivation of managers, and better STD management by service providers.

These baseline data confirm the feasibility of our community intervention trial. Power to detect a difference in STD prevalence during follow up should be ample, since male condom use is inconsistent, the intracluster correlation is small, and baseline STD prevalence is higher than assumed in study size calculations. Cluster randomisation has equalised known risk factors, and pair matching minimises imbalances in the relatively small number of randomisation units. The internal validity of these data appears sound: baseline STD was associated with unmarried status, having more than one recent sexual partner, and alcohol use. Misclassification of the STD outcomes is unlikely, given the high sensitivity and specificity of our tests. Misclassification of sexual behaviour variables is probable, but should not differ between the two groups. Selection bias due to selective loss to follow up will be assessed.

Two community intervention trials for HIV prevention have recently been conducted in Tanzania and Uganda, with superficially conflicting results. The magnitude of the STD epidemics in this region demands large scale intervention, while its relative poverty requires those efforts to be cost effective and replicable. Follow up results of our study will be known later in 2000. If female condom introduction leads to substantially reduced STD transmission, the Ministry of Health and international donor agencies will need to consider widening the availability and guaranteeing the affordability of the devices in this region with high STD prevalence among women.

Mr Peter Mwarogo, formerly of the Family Planning Association of Kenya (FPAK), and Mr Stephen Mucheke of FPAK, helped to design the intervention. We are particularly grateful for the untiring efforts of field study staff Dorcas Kungu, Ephel Khasandi, Nancy Muma, Catherine Wachira, and Joel Mutai. We thank Mario Chen-Mok and Hany Zayed for statistical support.

Before the fieldwork, the study was reviewed and approved by the Protection of Human Subjects Committee of Family Health International (FHI) with funds from the US Agency for International Development (USAID). The views expressed in this article, however, do not necessarily reflect those of USAID. Most of the female condoms were donated by the Department for International Development (DFID) of the United Kingdom. STD treatment kits were supplied by the Kenyan Ministry of Health. FHI is an international non-profit organisation that conducts research and provides technical assistance in health, family planning, STDs and AIDS.

Contributors: PJF, MK, and MW were centrally involved in all aspects of study design, implementation, and monitoring. JJB devised the specimen handling procedures, and hired and supervised the field team. MO trained the field staff, supervised the laboratory work and monitored the fieldwork. KAR monitored the informed consent procedures and conducted the data analysis. All authors participated in writing, editing, reviewing and approving the manuscript.

3 Fontanet AL, Saba J, Chandelying V, et al. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: Results from a randomized controlled trial. AIDS 1998;12:1851–9.
Baseline STD prevalence in a community intervention trial of the female condom in Kenya

P J Feldblum, M Kuyoh, M Omari, K A Ryan, J J Bwayo and M Welsh

Sex Transm Infect 2000 76: 454-456
doi: 10.1136/sti.76.6.454

Updated information and services can be found at:
http://sti.bmj.com/content/76/6/454

These include:

References

This article cites 11 articles, 1 of which you can access for free at:
http://sti.bmj.com/content/76/6/454#BIBL

Email alerting service

Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections

Articles on similar topics can be found in the following collections

- Contraception (247)
- Family planning (114)
- Drugs: obstetrics and gynaecology (160)
- Reproductive medicine (1356)
- Condoms (761)
- Chlamydia (841)
- Gonorrhoea (806)
- Ophthalmology (680)
- Drugs: infectious diseases (3182)

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/