Nonoxynol-9 for preventing vaginal acquisition of sexually transmitted infections by women from men

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Nonoxynol-9 does not protect against sexually transmitted infections, and there is some evidence that it may cause harm by increasing the incidence of genital ulceration. As such, this product cannot be advised for STI prevention.

RHL Commentary by Siegfried N

1. EVIDENCE SUMMARY

The review found good evidence that the use of nonoxynol-9, a vaginal microbicide, does not protect women against sexually transmitted infections (STIs). The ten randomized controlled trials included in the review reported outcomes for gonorrhoea, cervical infection, trichomoniasis, bacterial vaginosis, chlamydia and candidiasis, although not all the trials assessed each of these outcomes. Use of nonoxynol-9 did not significantly reduce the risk of any of these infections. The review reports that genital lesions such as ulcers, are significantly more likely to occur in women using nonoxynol-9, but this result (relative risk [RR]: 1.17; 95% confidence interval [CI]: 1.02–1.35) is only marginally significant.

The authors conducted an extensive search of a wide variety of appropriate databases. They attempted to include both published and unpublished studies by searching conference databases and contacting researchers and funding agencies working in the field. Reporting of the results of the search could be improved by stating the number of abstracts retrieved and the degree of overlap between the databases.

One reviewer extracted the data and another checked the data extraction. No method of arbitration is reported, so it is assumed that all differences were resolved by discussion.

Meta-analysis was conducted when the trials reported the same outcomes. The review states that the fixed effects model was used because the test for heterogeneity did not reach statistical significance. However, the tests for heterogeneity for the meta-analysis of gonorrhoea, cervical infection and candidiasis are significant at the p < 0.05 level. Only the relative risk for gonorrhoea is reported using the random effects model, although this is not made explicit in the review.

The data are comprehensively presented in the text and in the Table of Included Studies and Tables of Comparisons.
2. RELEVANCE TO UNDER-RESOURCED SETTINGS

2.1. Magnitude of the problem

Curable STIs represent a large burden of disease worldwide, with an estimated annual incidence of 340 million cases (1). Most cases occur in the developing world in the regions of South and Southeast Asia, sub-Saharan Africa and Latin America and the Caribbean. The highest rate of new cases per 1000 population is found in sub-Saharan Africa. In South Africa, 11 million STI cases are estimated to occur annually (2).

Despite the availability of effective treatment, bacterial STIs remain a significant public health challenge. Social stigma associated with STIs may prevent many people experiencing symptoms from seeking treatment. Complications can arise from both symptomatic and asymptomatic infections and, excluding HIV, STIs are second only to maternal factors as causes of disease, death and healthy life lost in women of reproductive age (1). STIs also act as co-factors in the sexual transmission of HIV(1). Globally there are currently 42 million people living with HIV/AIDS, with the bulk of these infections occurring in sub-Saharan Africa (3). Controlling STIs is therefore an important component of HIV prevention programmes and needs to be recognized as such.

2.2. Applicability of results

Six of the included trials were conducted in female sex workers working in high STI prevalence areas and therefore at high risk of acquiring these infections. However, there is no obvious reason why the efficacy results seen in sex workers would not apply to women who engage in sex less frequently.

The reviewer warns that it would be unwise to generalize the results (this presumably refers to the observed higher risk of genital lesions related to nonoxynol-9 use, although this is not clearly stated) to lower-risk women who use nonoxynol-9 occasionally as a spermicide for contraceptive purposes, rather than for protection against STIs. Given that the harmful effect of nonoxynol-9 is marginally significant, this seems a reasonable assumption.

Almost all the trials were conducted in developing countries, adding weight to the applicability of these results to under-resourced settings.

2.3 Implementation of the intervention

In October 2001, the World Health Organization released a report(4) stating that nonoxynol-9 does not protect against STIs. This statement is supported by current evidence. In South Africa, it is not included as a strategy in STI prevention programmes or national policy and has not been widely promoted as an effective intervention.

Should newer microbicides be found to be effective in future planned trials, implementation will need to include feasibility studies of uptake among women in terms of availability, ease of use, costs and impact on sexual function and enjoyment.

3. RESEARCH

Despite the finding that nonoxynol-9 is not effective, primary research on other microbicides in under-resourced settings will continue to be an important focus of research into STI control and HIV prevention. Given that microbicide use affords women choice and greater control of their risk of contracting an STI, evaluation of other microbicides is warranted. Since controlling STIs is part of HIV/AIDS prevention,
evaluation of microbicides is also part of HIV prevention research. If newer microbicides are shown to be effective, it will be essential to conduct feasibility studies not only among female sex workers, but also among sexually active women who do not engage in sex work.

In South Africa, the HIV Prevention Research Unit of the Medical Research Council in partnership with the National Institute of Health (USA) is conducting feasibility studies of microbicide use among sex workers and their steady male partners and clients (5). Three randomized controlled trials are planned that will assess the acceptability of the newer microbicides, dextrin sulfate (a vaginal gel) and PRO2000 (a sulfated polymer that is designed to block the attachment of HIV to human cells). An additional study in partnership with the Population Council is investigating the acceptability of the vaginal gel, Carraguarda, among HIV-infected men and women. Carraguarda thickens once placed in the vagina and inhibits viral entry; it also has antimicrobial properties.

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References


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