

FROM THE CLINICAL EFFECTIVENESS UNIT (CEU)

The members' enquiry service: frequently asked questions

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Introduction

The Clinical Effectiveness Unit (CEU) has received several enquiries from Faculty members regarding the use of nonoxynol-9 (N-9) and its effects, if any, on the vaginal mucosa and the risk of acquiring sexually transmitted infections (STIs). Here we present an illustrative response on the evidence regarding the efficacy and safety of N-9 lubricated condoms compared to condoms with non-spermicidal agents.

Illustrative CEU response

Clinical question

For women who require contraception or protection against STIs, are N-9 lubricated condoms safer and more effective than non-spermicidally lubricated condoms?

Summary of response

An expert group convened by the World Health Organization (WHO) and the Contraceptive Research and Development (CONRAD) Program produced a report with recommendations on the safety of N-9, and its effectiveness in protecting against pregnancy and STIs, including human immunodeficiency virus (HIV). This report concluded that there is no evidence that N-9 lubricated condoms provide additional protection against pregnancy or STIs compared with other lubricated condoms. It also recommended that they should not be promoted as adverse effects from the N-9 lubricant could not be excluded. Using N-9 lubricated condoms is, however, preferable to no condom use at all.

Studies comparing N-9 lubricated condoms to other condoms have focused on sex workers who may have multiple daily acts of intercourse with different partners. The low dose of N-9 on condoms is unlikely to damage vaginal mucosa unless they are used several times daily over a period of time. Women using N-9 lubricated condoms for contraception or to prevent infection may be encouraged to try other types of condoms, but should not feel that they have to discontinue condom use altogether.

Evidence-based medicine question (which guided our literature search strategy)

Population: Women who require contraception or protection against sexually transmitted infection.

Intervention: Nonoxynol-9 lubricated condoms.

Outcome: Efficacy and safety compared to other lubricated condoms.

Information sources

The CEU searched the sources listed in Table 1 in developing this Member's Enquiry Response.

Background

N-9 has been available as a spermicide since the 1950s and is found in most vaginal gels, creams, foams, films and pessaries. The estimated numbers of women using

spermicides varies worldwide, but data suggest that their availability over-the-counter makes them particularly appealing to unmarried women and young people.¹ All spermicides available in the UK contain N-9.² The concentration of N-9 ranges from 1% in lubricated condoms to 28% in vaginal contraceptive film.³

At the 13th International Aids Conference in July 2000, preliminary results of a randomised controlled trial were presented, which showed a higher rate of new HIV infections in women using a N-9 spermicidal gel than in those using a placebo gel.⁴ On account of these findings, the WHO Department of Reproductive Health Research held a technical consultation in 2001, in partnership with the CONRAD Program, to review the evidence available on N-9. A report of this consultation was subsequently published with advice on the safety of N-9 and its effectiveness in protecting against pregnancy and STIs including HIV.¹

Evidence reviewed

The Cochrane Library, MEDLINE and EMBASE from 1996 to 2004

Effects on vaginal mucosa. To obtain safety data, the WHO/CONRAD report¹ reviewed 16 studies. Comparisons between individual studies were difficult, however, due to different products, doses and frequencies of use. Most of the data on the effect of N-9 on vaginal mucosa have been obtained from studies where vaginal gels, suppositories or impregnated sponges were used, rather than N-9 lubricated condoms. In general, there was a trend towards a greater frequency of epithelial disruption with greater frequency of use and higher doses of N-9. Infrequent use of products containing low doses of N-9 is likely to be safe.

Contraceptive efficacy. Several studies on the contraceptive efficacy of N-9 in different products were reviewed. Regarding N-9 lubricated condoms, one use-effectiveness trial⁵ reported a 2.1% probability of pregnancy among typical users for a 12-month duration.

Table 1 Sources used in developing the Member's Enquiry Response

Source searched	Information identified
The National Guidelines Clearing House	No relevant information
Existing FFPRHC and RCOG Guidance	No relevant information
WHO publications: <i>Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use</i> (2000) and <i>Selected Practice Recommendations for Contraceptive Use</i> (2002)	No relevant information
The Cochrane Library	See text
MEDLINE and EMBASE from 1996 to 2004	See text

FFPRHC, Faculty of Family Planning and Reproductive Health Care; RCOG, Royal College of Obstetricians and Gynaecologists; WHO, World Health Organization.

Only pregnancies leading to a live birth were reported, and men in the study were predominantly older as 26% were aged between 40 and 44 years, 27% were aged between 45 and 49 years and 24% were aged over 50 years. Low coital frequency was also reported and female partners were noted to be of lower fecundity.

Prevention of STIs. Regarding the effectiveness of N-9 for STI prevention, the report reviewed one randomised trial conducted in genitourinary medicine clinics in Cameroon, that compared the effectiveness of condoms plus an N-9 gel to condoms alone for prevention of gonococcal and/or chlamydial infection primarily, and HIV secondarily.⁶ Women who used the gel had a 20% higher incidence of gonorrhoea or chlamydia or both than women who used condoms only. One in vitro study is cited,⁷ which showed that N-9 killed HIV when added to condoms in a simulated model for intercourse. However, it is unclear how these results can be extrapolated to condoms pre-lubricated with N-9 during manufacture.¹

The overall conclusion of the WHO/CONRAD summary report is that there is no evidence that N-9 lubricated condoms provide additional protection against pregnancy or STIs compared with condoms lubricated with other products. Adverse effects from the N-9 lubricant cannot be excluded, and therefore N-9 lubricated condoms should not be promoted. However, it is better to use N-9 lubricated condoms than no condoms at all.

Aside from this report, the CEU review of the literature identified two randomised controlled trials,^{8,9} one of which looked at the use of N-9 lubricated condoms among 70 female prostitutes for the prevention of HIV and other STIs.⁸ No association was found between the dose of N-9 in condom lubricants and reported symptoms or signs of genital tract inflammation. Higher doses of N-9 were, however, associated with more polymorphonuclear leukocytes identified on vaginal wall smears. The second study compared the use of N-9 lubricated condoms with silicone lubricated condoms among Dominican sex workers.⁹ No significant differences in cervical infection rates, trichomoniasis or discomfort rates were found between the two groups, and the study concluded that the plain silicone lubricated condoms are as effective as N-9 lubricated condoms.

Conclusions

Studies comparing N-9 lubricated condoms to other condoms have focused on sex workers who may have

multiple daily acts of intercourse with different partners. Infrequent use of products containing low doses of N-9 was felt to be safe by WHO/CONRAD, and the low dose of N-9 on condoms is unlikely to damage tissue unless they are used several times daily over a period of time. The WHO/CONRAD report found no evidence to suggest that N-9 lubricated condoms offer any additional benefits to condoms with other lubricants. However, the report is clear that the use of N-9 lubricated condoms is preferable to no condom use at all.

Disclaimer

The advice given in this Member's Enquiry Response has been prepared by the FFPRHC Clinical Effectiveness Unit team. It is based on a structured search and review of published evidence available at the time of preparation. The advice given here should be considered as guidance only. Adherence to it will not ensure a successful outcome in every case and it may not include all acceptable methods of care aimed at achieving the same results. This response has been prepared as a service to FFPRHC members, but is not an official Faculty Guidance product; Faculty Guidance is produced by a different and lengthier process. It is not intended to be construed or to serve as a standard of medical care. Such standards are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances. Members are welcome to reproduce this Response by photocopying or other means, in order to share the information with colleagues.

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