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POTENTIAL OF SPERMICIDALLY LUBRICATED CONDOMS AS AN STD DETERRENT

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INTRODUCTION

Prevention is our greatest weapon agains STDs, or sexually transmitted diseases, and barrier methods of contraception are one of our best means of prevention. Since it is generally assumed that both condoms and spermicides can prevent infection with sexually transmissible organisms, it is logical to suppose that joint use of these two methods would enhance the protective effect. So far, however, evidence for this supposition is lacking. Although condoms are widely used, they are relatively poorly studied, especially the new class of spermicidally lubricated condoms.

In this presentation I will review the laboratory and epidemiologic evidence for the effectiveness of condoms and of spermicides in preventing the transmission of STDs. It will be apparent that independently they can have an important role in slowing the spread of STDs. I will then suggest, based on the limited information available, that joint use of the two methods, as in spermicidally lubricated condoms, could be the best choice both to prevent pregnancy and to deter the spread of disease.

LITERATURE REVIEW

Condoms in vitro

The AIDs epidemic has stimulated laboratory work on the permeability of condoms to various disease organisms. One limited *in vitro* study suggested that the AIDs virus cannot pass through latex or natural membrane condoms.[1] Only five condoms were tested, though. A more recent study found that none of 30 condoms leaked HIV, and that when spermicidally lubricated condoms were deliberately ruptured the HIV

organisms were inactivated.[2]

HIV is approximately 120 nanometers in diameter. Another STD virus, the hepatitis B virus, is only one third the size of HIV. The herpes simplex virus is larger than HIV, about 200 nanometers, and the cytomegalovirus is about 300 nanometers. The tiny hepatitis B virus may be able to pass through natural membrane condoms,[3] while the larger herpes virus and cytomegalovirus do not pass through any type of condom.[4,5] Experts debate whether HIV, intermediate in size, can pass through natural membrane condoms, which exhibit pores under scanning electron microscopy. It may be that only latex condoms should be recommended for the prevention of HIV infection, since electon microscopy of stretched latex condoms had demonstrated surface irregularities but no pores.[6]

Condoms in vivo

What about the human data on the association between condom use and STDs? A series of studies among both men and women have shown a protective effect of condoms against bacterial STDs, including gonorrhea, mycoplasma and hospitalized cases of pelvic inflammatory disease.[7] Several studies detected statistically significant reductions in STD risk for condom users; the STD risk for condom users relative to non-users ranged from zero up to 1.35. In these studies, though, the condom group wasn't necessarily comparable to the non-users group. Condom users may have been different than non-users in important but unmeasured ways. Also, the regularity of condom use was unknown yet is critical to the evaluation of prophylaxis.[7]

Most of this earlier work looked at gonorrhoed and other bacterial STDs as the disease outcomes. Of greater current interest is the effect of condom use on the transmission of HIV, and here some preliminary data are available. In 1985, 377 female prostitutes were enrolled in a study of sexual practices and HIV seroprevalence in Kinshasa, Zaire.[8] Of these women 23 percent reported that at least one of their clients had used a condom in the past year. The HIV seroprevalence among the eight women reporting condom use by half or more of their partners (not one of 8) was significantly lower than the 34 percent prevalence among women reporting less frequent or no condom use. The two groups were similar with regard to other risk factors for HIV.

The Centers for Disease Control's (CDC) ongoing HIV prevalence study of U.S. prostitutes[9] found that of 546 prostitutes interviewed, 11 percent of those reporting unprotected vaginal intercourse were seropositive. Of the 22 prostitutes who used condoms for every episode of vaginal intercourse, not one was seropositive ($p=0.10$).

One U.S. study followed 24 uninfected sexual partners of AIDs patients for 12 to 36 months, with a median of 24 months. Among 10 couples who routinely used condoms, only one partner became with HIV. In the 14 couples who did not use condoms, 12 partners became infected ($P=0.0005$

by Fisher's exact test).[10]

In addition, two uncontrolled studies among prostitutes provide anecdotal support for condom prophylaxis. In one study of 101 Danish prostitutes, none was seropositive for HIV[11] A second study included 448 licensed prostitutes in Nuernburg, West Germany.[12] Again, none of 399 tested was seropositive. The Danish women reported that 68 percent of their episodes of vaginal intercourse involved condom use, and 97.5 percent of the German women had vaginal intercourse with condoms. Lesser percentages of other sexual acts were protected by condoms. These two studies, however, are difficult to interpret since neither included a control group.

Spermicides in vitro

Spermicides also show promise as a prophylactic measure. Laboratory studies have demonstrated that nonoxynol-9 and various commercial spermicidal products inactivate a variety of STD pathogens,[13] including the AIDs virus. In the HIV study, virus inactivation occurred within 60 seconds of exposure to a nonoxynol-9 concentration of 0.05 percent or greater; at this concentration, nonoxynol-9 was also toxic to the lymphocytes infected by HIV.[14,15] Commercial spermicidal preparations contain at least 20 times this concentration. As I noted before, spermicidally lubricated condoms have also proven to be effective in the laboratory against HIV, even when ruptured.[2]

Spermicides in vivo

Numerous epidemiologic studies have shown that use of a spermicidal contraceptive method substantially reduces the risk of the most common bacterial STDs–gonorrhea and chlamydial infection.[7,13,16] Different study designs, including case-control studies, cohort studies and cross-sectional studies have consistently found that spermicide use reduces the risk of gonorrhea by 30 to 90 percent. Three early, and limited, clinical trials also detected significant reductions in the rate of endocervical gonorrhea among spermicide users compared with non-users.

The most recent study, that was conducted by my organization, Family Health International (FHI) in collaboration with the Thailand Ministry of Public Health, was a randomized clinical trial that evaluated the protection by the Today® contraceptive sponge against STDs.

The sponge is made of polyurethane and contains one gram of nonoxynol-0. The dimple side fits against the cervix, and a loop facilitates removal.

In our study, after gaining the cooperation of four large Bangkok massage parlors, disease-free female parlor employees were invited to participate. Over 300 high-risk women were assigned either to use sponges

at every intercourse, or to receive no intervention. All women were using an effective contraceptive method. The parlor employees were followed weekly for up to six weeks or until infection occurred. They reported an average of about 10 sexual partners per week. We found that sponge use reduced the risk of endocervical chlamydial infection by about one third (a relative rate for sponge users compared with non-users of 0.67) and of gonorrhea by two thirds (a relative rate of 0.31).[16] This was the first study of the association between spermicide use and chalamydial infection.

SPERMICIDALLY LUBRICATED CONDOMS

Condoms and spermicides, which as we have seen are effective against STDs, play an important family planning role in many places around the world, especially in Western nations. Yet they are little used in Africa. Some of the reasons offered for the limited appeal of condoms are: decreased sensitivity, inconvenience, a historic association with illicit sex, and the perception of low effectiveness. But better information and marketing techniques can change attitudes, and innovation is producing more acceptable and more effective devices.

In the 1970s Potts and McDevitt hypothesized that a condom with a standard lubricant supplemented with spermicide might be more effective as a contraceptive than either plain condoms alone or spermicide alone.[17] Their consequent study is the only investigation ever published on the contraceptive efficacy of spermicidally lubricated condoms. The devices were made available to 416 mail-order condom users in 1972. Three hundred ninety seven users completed a questionnaire after two years of use. There were only six accidental pregnancies, yielding a very low pregnancy rate of 0.83 per 100 couple-years of use.

The couples judged that the experimental condoms improved sensitivity compared with standard condoms. Although minor complaints were reported, including problems with the packaging of the devices, their unpleasant smell and taste, staining of clothing, some irritation and messiness, over 87 percent of the couples stated that they would buy the spermicidally lubricated condoms if they were commercially available. And remarkably, only three out of 397 couples discontinued use because they were dissatisfied with the product.

In the 1980s, a U.S. pharmaceutical firm tested the acceptability of a spermicidally lubricated condom in 30 men ranging from 19 to 46 years of age. [18]None of the men reported penile irritation.

In another U.S. investigation, the volunteer couples found the nonoxynol-9 condoms to be desthetically pleasing, and simulated rupture tests found that the spermicidally lubricated condoms were as effective as standard condoms plus spermicidal foam.[19]

To supplement the findings of these studies, all conducted among highly motivated couples in the developed world, FHI is currently conducting acceptability studies of spermicidally lubricated condoms in five

developing countries. Condom users will be provided two kinds of spermicidally lubricated condoms and asked to use them for one month. The U.S. Agency for International Development, or AID, presently supplies several hundred million condoms each year for distribution around the world. If these new condoms prove to be acceptable to typical users, AID may modify its condom purchase policy to include the devices. We will then be able to address the dearth of information about spermicidally lubricated condoms and to initiate quantitative studies of their prophylactic effect compared with standard condoms alone or spermicides alone. Certainly, these new and improved devices cannot be any less effective than standard condoms in the prevention of pregnancy and disease.

DISCUSSION

Both *in vitro* and *in vivo* studies have demonstrated that barrier contraceptive methods provide important non-contraceptive benefits. Nevertheless, we must keep in mind that, looking solely at their contraceptive effect, neither condoms nor spermicides completely eliminate the risk of pregnancy even when consistently used. Condom pregnancy failures can occur due to incorrect use. Even with correct use, semen may be lost in several ways: prior to ejaculation and before the actual application of the condom; via leakage after ejaculation through holes that may be present in the membrane; via spillage after ejaculation; and following condom rupture during intercourse. A failure rate as low as 1 pregnancy per 100 couple-years of consistent condom use has been reported for highly motivated couples, but rates as high as 22 pregnancies per 100 couple-years have also been reported for less carefully selected users.[20] With regard spermicides, reported failure rates range widely from 4 to 31 pregnancies per 100 couple-years of use.[21]

Although the protection offered by these methods isn't perfect, it is substantial. Users must be aware, however, that the pattern of use for disease prevention has to be different than that for pregnancy prevention. Condoms or spermicides must be used at *every* sexual encounter to prevent STD transmission--for sterilized couples, during menstruation, after surgical or natural menopause, and during vaginal, anal and possibly oral intercourse. Although a woman may be at risk of pregnancy for only 40 to 50 days of the year, she is at risk of contracting an STD for all 365 days.

In conclusion, momentous public health decisions are being made on the grounds of common sense substantiated a small amount of inconclusive clinical evidence. With no alternative, Fe are justified in recommending condoms and spermicides for the prevention of STDs, and in believing that spermicidally lubricated condoms offer the best protection. Yet more data are needed to confirm and measure that protection. Clinical trials and cohort studies following populations at high risk of infection, including prostitutes and STD clinic attendees, must be

conducted as opportunities develop. The acceptability of and compliance with use of these methods must be tested. Innovative marketing approaches have broadened the acceptability of condoms in many countries, and we must continue on this path. Education and communication programs must be designed, implemented and evaluated rapidly. With our experience in counseling and provision of contraceptives, the family planning community potentially has much to contribute to STD containment efforts.

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