How Safe are Safes?

Efficacy and effectiveness of condoms in preventing STDs

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SUMMARY

Condoms are widely promoted for preventing sexually transmitted diseases, with an implicit message that a properly used condom will ensure that you are safe from STDs. A literature review shows that little solid evidence supports this belief.

RÉSUMÉ

L'utilisation des condoms est largement publicisée pour prévenir les maladies transmissibles sexuellement, avec un message implicite que, utilisés adéquatement, ils assurent une protection contre les MTS. Une revue de la littérature révèle une faiblesse au niveau de la qualité des données et ne permet pas d'appuyer cette croyance.

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THE MESSAGE THAT USED TO BE printed on the front of condom vending machines in men's washrooms was "For the prevention of disease." The message that is now being sent out in television advertisements, billboards, brochures, posters, and every other medium is "Condom use prevents AIDS and other STDs." A recent article on prevention suggested that we counsel our patients about "the use of barrier methods to prevent sexually transmitted diseases, to prevent HIV infection."[1]

But how effective are condoms? Do they really offer reliable protection against viral, bacterial, and other sexually transmitted diseases? What is the quality of the evidence? In this review, I attempt to answer these questions, based on a critical appraisal of available literature.

METHODS

I searched the English-language literature with Grateful Med software to access MEDLINE, for the years 1986 to 1991, using the MeSH terms condom, sexually transmitted disease, and prevention and control. I examined original research articles, but not review articles, news items, or editorials. Two types of articles were collected: laboratory studies relating measurements of condom permeability to infectious agents, and clinical studies comparing rates of sexually transmitted diseases in groups using or not using condoms. I examined the references from the articles to ascertain whether any other articles met the search criteria. To discover additional articles, I checked the references from a chapter on prevention in the most recent edition of an authoritative text on STDs.[2]

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RESULTS

The search found 51 articles listed under the terms condom, STD, and prevention and control. Of these, only six fit the search criteria. The reference lists from those six articles yielded a further eight articles. A manual search of the last 6 years' issues of several appropriate journals produced two more. The text on STDs[2] provided no articles except those already found by the search strategy.

Evidence

Efficacy. In this context, efficacy is defined as the reduction in STD

Table 1. **Summary of studies on condom use**

STUDY	DESIGN	POPULATION (N)	DISEASE (OUTCOME)	MEASURE OF EFFECT	COMMENTS
Lindan et al 1990[7]	Cross sectional	STD clinic in San Francisco (300)	Any STD	Relative risk = 60%	95% CI = 0.4-0.9
Darrow 1989[8]	Cross sectional	STD clinic in Sacramento, Calif.	Gonorrhea	20% positive among always used, 27% positive among never used	$P = 0.87$
Mann et al 1987[9]	Cross sectional	Prostitutes in Zaire (85)	AIDS	0% of 8 frequent users, 33% of 77 infrequent users	$P = 0.046$
Nzila et al 1991[10]	Cross sectional	Prostitutes in Zaire (1233)	HIV	9% regular users among HIV-positive, 14% regular users among HIV-negative	$P = 0.009$
Cameron et al 1991[11]	Cross sectional	Prostitutes in Nairobi (423)	Genital ulcer disease	16% of regular users, 45% of non-users (odds ratio 4.8)	$P < 0.02$
Fischl et al 1987[12]	Cohort	Spouses of people with AIDS (45)	HIV seroconversion	10% of 10 users, 88% of 14 non-users	At enrolment, 2 users positive, 9 non-users positive
Ngugi et al[13,14]	Cohort (randomized, controlled trial?)	Prostitutes in Nairobi (595)	HIV seroconversion	46% of 50 users, 71% of 28 non-users (odds ratio 0.34)	$P < 0.05$, 95% CI = 0.13-0.92

transmission achieved by condom use in ideal circumstances. An approximation can be measured in the laboratory, using microbiological culture techniques and mechanical models.

In 1986, Conant and colleagues[3] used a 12-mL syringe and tissue-culture medium to study the permeability of different types of condoms to human immunodeficiency virus (then called AIDS-associated retrovirus) and mouse retrovirus. In 10 trials, with both "natural" and latex condoms, no virus was transmitted at all, despite high titres of virus used.

A similar study used hepatitis B surface antigen (HBsAg) with a radioactive label and a mechanical vibrator.[4] This study found that five brands of latex condoms did not leak radioactive tracer, but that the only natural condom examined (made from sheep intestinal membrane) did leak tracer. The authors suggest that, because HBsAg is only half the size of the hepatitis B virus (HBV), using latex condoms would make the transmission of this infection unlikely.

A larger study examined three different viruses (HBV, herpes simplex, and cytomegalovirus [CMV]) and six different brands of condoms (five latex, one natural), using molecular hybridization and viral culture techniques.[5] Each condom was tested in triplicate for each virus. In all of the combinations, leakage occurred only with hepatitis B virus in natural condoms.

A possible explanation for this result lies in the size of the virions being studied. Herpes simplex and CMV are 150 to 200 nm in diameter (HIV is approximately 120 nm), much larger than the 42-nm hepatitis B virus, which presumably can pass through the pores in natural condoms. These pores have been shown through an electron microscope to be up to 1.5 μm in diameter, or 10 to 20 times the size of the viruses involved.[5] Latex condoms, viewed under the electron microscope, show no such pores.

Other laboratory studies, published before the period of this review, also show latex condoms to be effective barriers against herpes simplex virus, CMV, *Chlamydia trachomatis*, and *Neisseria gonorrhoeae*.[6] The overwhelming weight of laboratory evidence indicates that latex condoms are indeed impermeable to the common STD agents.

Effectiveness. Few studies evaluate the effectiveness of condoms (ie, the protective effect in situations of actual use). *Table 1* summarizes seven studies[7-14] that fit the criteria outlined earlier: publication date after 1986, and original research on condom effectiveness in preventing STDs.

The first group of studies[7-11] is cross sectional. In all cases, the subjects enrolled were from high-risk groups. They were asked about condom use with their most recent episode of intercourse,[7] since their last clinic visit,[8] and in general.[9-11] They were then tested for the STD in question, and the relationship between reported condom use and presence of the STD was noted.

The studies use different statistics to report results. For instance, the first[7] describes a relative risk of 0.6; condom users were 40% less likely to be diagnosed with an STD than those who did not use condoms. The largest study,[10] performed in Zaire, reported results from the opposite perspective. The authors stated that regular condom use was reported more often by women who were HIV-negative (14%) than by women who were HIV-positive (9%). The authors also reported, however, that after multivariate regression analysis, condom use (or lack thereof) was not associated with HIV infection.

Only one study failed to show a protective effect of condoms[8]; this study, although published in 1989, was performed in 1971. No explanation was given for the 18-year hiatus between performing and reporting the study.

The last two studies summarized in *Table 1* give evidence that is methodologically stronger. Fischl and her co-authors[12] used a cohort design, following 45 spouses of people with AIDS over a period of 1 to 3 years. Ten spouses were no longer having sexual contact. Of the 23 who reported not using condoms, nine were seropositive at the outset of the study and 12 of the remaining 14 became positive during the study. Among the 12 spouses regularly using condoms, two tested positive for HIV at enrolment, and only one of the remaining 10 became positive. Overall, of 26 seropositive spouses, three reported regular condom use; of 19 seronegative spouses, 10 reported using condoms regularly ($P < 0.001$).

The final article describes itself as "a complex controlled clinical trial consisting of three arms."[13] Another article,[14] by the first two authors of the article just cited, presents the same data and same results. The second article lists the first as a reference, albeit with the wrong title, but does not make it clear that it is a duplicate publication. The study investigated prostitutes in Nairobi. An initial group of 595 was divided into two cohorts (no randomization was mentioned). One cohort of 229 was asked to attend clinic every 2 weeks; the other cohort of 266 attended clinics when they wished (the figure 266 is apparently wrong – the numbers do not add up – and the other study gives the correct figure, 366). Both cohorts were offered educational community meetings and had the services of community health workers who acted as informal health educators. Later in the study, individual counseling sessions were offered to women "in an unselected manner as they presented to the clinic." Again, randomization is not mentioned and presumably women who received counseling could have been from either of the earlier cohorts. Later, 205 prostitutes were recruited as a control group.

The women were asked about condom use. Then, retrospectively, the prostitutes were divided into three groups for analysis: those from the original groups who received counseling ($n = 91$ in the text of the article, $n = 94$ in a table), those enrolled in the initial groups and not counseled ($n = 67$), and those newly recruited ($n = 205$). Condom use in all three groups was low, 7% to 10%. Reported condom use increased in the two intervention groups. The authors report that any condom use resulted in a reduction by a factor of two thirds in the risk of seroconversion (odds ratio = 0.34),

stating, in the abstract but not at any point in the text, that 20 of 28 non-users seroconverted, compared with 23 of 50 women who sometimes used condoms.

Again the numbers are problematic. Presumably, women are either non-users or use condoms at least some of the time (we are told that only one woman reported 100% use). The denominator, the number of women studied, seems to have shrunk to 78 (28 + 50), from the previous 363 (91 + 67 + 205, or was it 94 + 67 + 205?). That number in turn bore no relationship to the previous 595 (229 + 266, or was it 229 + 366?). Finally, we are not told by these authors the seroprevalence of HIV in the study population overall.

I describe the methodological and arithmetic flaws in this paper because it claims to be a "controlled clinical trial" (albeit not randomized) and the authors might have been able to present us with fairly strong evidence of condom effectiveness. As it is, the flaws lead us to doubt seriously the validity of the results.

Several other studies look less directly at the issue of condom effectiveness in preventing STDs. A study of the HIV status of 568 American prostitutes[15] mentions that none of 22 prostitutes whose partners always used condoms were HIV-positive, while 11% of the other 546 were positive. However, after controlling for intravenous drug use, there was no statistically significant difference ($P = 0.10$).

A case-control study[16] examined women who were infertile due to tubal occlusion or adhesions and found that women who had ever used barrier methods of contraception had a lower risk of tubal infertility (relative risk = 0.6; 95% confidence interval 0.5 to 0.8). Presumably the tubal occlusion would often have been due to previous pelvic inflammatory disease, in turn due to an STD.

Finally, a case-control study[17] of women with invasive cervical cancer showed that condoms do not significantly reduce the risk of this disease, after controlling for confounders such as age and lifetime number of sexual partners (relative risk = 1.2; 95% confidence interval 0.9 to 1.6).

In all these research studies, randomized, controlled trials are notably absent. Setting up a randomized, controlled trial now to study the effectiveness of condoms would be ethically difficult, given current information on efficacy. It would also be practically difficult because of the wide availability of condoms and the amount of media attention advocating their use. In the absence of randomized, controlled trials, evidence of condom effectiveness must be obtained from research methodologies that are not as rigorous and thus do not provide as convincing proof.

I am also concerned about whether these studies can be generalized. Many reports are from Africa, especially Kenya, where HIV infection prevalence is very high and STDs, such as genital ulcer disease, are common. Other differences, including the general health status of the populace, cultural beliefs, and the availability and use of over-the-counter antibiotics, all influence STD prevalence and transmission patterns. Even the studies done in North America examined people (STD clinic users, prostitutes, spouses of people with AIDS) very different from those in my practice.

Conclusion

Safes are very safe in the laboratory. Several different experimental models show latex condoms to be 100% impervious to a variety of STD pathogens, even small viruses.

But things are different in the real world. Despite widespread information campaigns, people at risk often do not use condoms because of cost, cultural beliefs, impatience, unplanned passion, and many other factors. When condoms are used, they are sometimes used incorrectly: with oil-based lubricants that weaken them, after mucosal contact has already occurred, or only during certain types of sexual contact. Finally, even if they are used, and used with good intent, condoms can fail: they slip off; they break; they leak.

The absence (or, more fairly, the impossibility) of properly done randomized, clinical trials makes it difficult to define or measure effectiveness. Cross sectional and cohort studies, with their inherent limitations, do suggest that consistent use of latex condoms will reduce the risk of contracting an STD. According to the evidence, risk will be reduced by a factor of

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three or four (ie, the risk of catching an STD if not wearing a condom is roughly three or four times higher than if you do use a condom properly).

Given the flaws in the studies discussed and the fact that none of these studies applies to my practice population, what would I now say if one of my patients asked me, "Doc, do condoms work? Should I (or my partner) use one?" I would say that they help to reduce the risk; that they do not prevent all STDs all of the time; and that other measures, such as limiting number of partners and getting screened for STDs, are at least as important. ■

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