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Efficacy of barrier methods in contraception

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HISTORICAL PERSPECTIVE

Barrier methods are the oldest and also the least studied methods of contraception. Only a few researchers have tried to measure their effectiveness. However, at this time when the need for contraception has never been greater, when a variety of bacterial and viral sexually transmitted diseases (STDs) are spreading rapidly and with the new terror of acquired immune deficiency syndrome (AIDS), objective information is urgently needed on the efficacy of barrier methods both in stopping pregnancy and deterring STDs.

Sheaths were described by Fallopio in 1564 and the word condom first appeared in print in 1717 and is probably derived from the Latin *condus* or receptacle. Vaginal pessaries, or caps, were described at the beginning of the 19th century and the commonly used diaphragm was designed in the 1880s by a physician named Hesse. In 1885 the English pharmacist, Walter Rendell, began making spermicides and Rendell's pessaries are still sold in Europe.

The early marketing of contraceptives was underground and exploitive. Beginning in the 1920s the Birth Control Investigation Committee in Britain and the US National Committee on Maternal Health began a more scientific approach. Measures of quality control were formulated and in 1932 Raymond Pearl introduced the idea of pregnancies per 100 woman years of exposure (HWY)[1]. With the invention of the pill and the renaissance of IUDs in the 1950s and 1960s efficacy rates for these methods were carefully studied, but the familiar barrier methods were grandfathered into the new and rigorous approval processes set up by the FDA and other drug regulatory authorities. Once a method is sold over the counter and widely used it is usually difficult to recruit and follow a large group of users when regular clinical supervision is not obligatory.

The TODAY sponge, a new method, was approved by the FDA in 1983 after clinical trials which, because it was a novel method, were more rigorous than any previously applied to a barrier method[2]. The Prentiff Cervical Cap, a 19th century method, was approved for US marketing in 1988. A new female barrier method, the Femshield (or female condom), may be submitted

Table 1 Female barrier methods

	Pregnancies per HWY
Creams	4.7– 9.1
Diaphragms	2.2–23.0
Foams	1.8–29.3
Foaming tablets	2.3–38.3
Jellies	2.7–36.1
Suppositories	0.0–21.1
Cervical caps	7.6– 9.3

From D.A. Edelman (1984)[1]

for FDA consideration shortly, but no efficacy data are yet available.

Barrier methods are major methods of family planning in some countries (e.g. Japan and Bangladesh), but little used in others (e.g. USA and Malaysia).

PREVENTION OF PREGNANCY

Variations in proper use, risk-taking behavior, fecundity and frequency of intercourse are bound to influence effectiveness rates obtained in any study. Researchers are sometimes guilty of applying a double standard to measures of contraceptive effectiveness. Women who participate in oral contraceptive clinical trials are removed from the study if they do not take their pills regularly. After all, no one expects the pill to work effectively if it is used incorrectly or irregularly. However, users of barrier methods are rarely removed from a clinical trial if they fail to use their assigned method every time. We accept these risks with barrier methods, yet we exclude them in clinical trials to determine the effectiveness of systemic methods. Is it any wonder, therefore, that the use-effectiveness of systemic methods is closer to their theoretical effectiveness, while a large gap often exists between the theoretical and obtained use-effectiveness recorded for barrier methods?

Efficacy studies on barrier methods report wide variations in pregnancy rates (Table 1). Fisher, reporting on family planning clinic users in Oxford, England between 1935 and 1950, found a pregnancy rate for the condom of 7.5 per HWY[3]. The Indianapolis study followed middle and upper income US couples over a fertile lifetime and found a failure of 6 per HWY[4]. Peel, in Hull, England, followed 312 newly married couples over 5 years and found condom users had a failure rate of 3.9 and consistent users a rate of 1.6 per HWY[5]. Vessey and Wiggins, also in England, found a pregnancy rate for the diaphragm among married women over 25 of 2.4 per HWY[6].

Tietze and Lewitt found a pregnancy rate of 28.3 per HWY for foam, 36.8 per HWY for jellies and creams used alone and 17.9 per HWY for diaphragms and spermicides used in the same clinic[7]. A 1-year cumulative life-table rate of 17.4 per HWY was found in the National Institutes of Health (NIH) sponsored, Family Health International (FHI) conducted studies on the TODAY sponge containing nonoxynol-9[2]. In a study of 617 users of the cervical cap the life-table pregnancy rate per HWY was 16.6[8]. NeoSampoon, which is a foaming tablet containing menfegol that is quite widely used in

Table 2 Diaphragm: disparate failure rates in similar studies

Study	*n*	*Pregnancies per 100 women during first 12 months of use*
Lane, 1976	2168	2.1
Edelman, 1984	721	12.5
Bernstein, 1987	572	16.7

From Hatcher, R., Guest, F., Stewart, F. *et al.* (1988)[24]

Table 3 Use of the diaphragm: practice makes perfect

Duration of use (months)	*Pregnancy rate* (HWY)
5–23	4.2
24–29	3.7
60+	1.4

From M.P. Vessey and P. Wiggins (1974)[6]

some developing countries, had a gross life-table pregnancy rate of 6.5 among 150 users in Dhaka, Bangladesh[9]. A study of the beta-blocker, propranolol, used as a contraceptive found a life-table pregnancy rate of 3.4 in a group of 198 women in Chile[10]. Alkylphenoxy polyethoxy ethanol (agent 741) which is used as a spermicide in China is similar to nonoxynol-9 in action and comparable in animal toxicology[11].

Even if we had more extensive data on pregnancy rates for barrier methods of contraception, we would still find that the failure rate for coitally dependent methods varies widely (Tables 2 and 4). It is lower among the older married couples than younger individuals and the effectiveness rate for all barrier methods probably improves with duration of use (Table 3). Interestingly, there is a possible association between failure with a barrier method and other risk-taking behaviors, such as smoking (Table 5).

For a long time into the future, decisions about the use of barrier methods are likely to remain a mixture of limited data and common sense assumptions. For example, the addition of spermicides to condoms would appear to be a common sense way of making the method more effective but would take an impossibly large clinical study to conclusively demonstrate a statistically lower failure rate than for plain condoms[12]. Barrier methods deserve greater support by physicians, who are not likely to distribute condoms or spermicides, but can encourage their use in appropriate circumstances. If, as seems likely, failures are commonly the result of poor compliance, then improved clinical and educational measures (e.g. the TODAY sponge runs a toll-free telephone information service) must be encouraged.

PREVENTION OF STDs

If accurate data on pregnancy failure rates for barrier methods have been difficult to acquire, information on STDs is even harder to come by. Until the second half of the 19th century, condoms were used almost exclusively as prophylactics but the evidence of protection against disease was based on

Table 4 Effectiveness of diaphragms, selected studies, 1973–83

Author, date, country	*Type of study*	*No. of women*	*Characteristics of women*	*Pregnancy rate*
Edelman 1983, US	Clinic-based	721[a]	47% under age 25, 49% unmarried, 76% with less than 13 years of education	12.5
Lane *et al.* 1976, US	Clinic-based	2168[a]	61% under age 25, 71% unmarried	1.9–2.2
Ryder 1973, US	Population-based	1186	Age 45 or younger, ever married	23.0
Schirm *et al.* 1982, US	Population-based	368[c]	Age 15–44 currently married	18.6
Vessey *et al.* 1982, UK	Clinic-based	4217[d]	Age 25–39 at recruitment, married, all had used diaphragms for at least 5 months	1.9

[a]Number of women who began study
[b]Per 100 women at 1 year of use (1-year cumulative life-table rate)
[c]Source: Ford 1978 (145)
[d]Source: Vessey *et al.* 1976 (397)
From *Population Reports*, New developments in vaginal contraception, Series H, No. 7, 1984[25]

Table 5 The failure rate of condoms is higher among couples where the woman smokes

	Cigarette smoking by women		
	Never	*Ex-*	*Current*
Adjusted failure rate	2.7	3.5	3.8

From M.P. Vessey, L. Villard-Makintosh, K. McPherson and D. Yeates (1988)[26]

the common sense assumption that they kept infected material apart.

Air-burst and water tests are common quality control items in condom manufacture and neither bacteria nor viruses will pass an intact latex condom. (The hepatitis B virus is the smallest, 42 nm; human immune deficiency virus (HIV) is approximately 120 nm in diameter.) Unfortunately condoms occasionally tear in use. FHI is designing studies to correlate the results of quality control tests with the probability of breakage at intercourse, but to date no information exists. Latex condoms can be rapidly damaged by oil-based lubricants and can deteriorate if stored at high temperatures for long intervals, as occurs in many developing countries.

Only nine clinical studies exist of the impact of condom use on STD

transmission[13]. Compliance is always going to be uncertain but in one study of 247 condom users in London the prevalence of herpes was 0.8% versus 1.7% among non-users[14]. Thus, condoms appear to provide a degree of protection against STDs and, as with pregnancy, infection is more probably due to non-use than mechanical failure.

A worldwide campaign to use condoms to slow the spread of AIDS has been mounted, yet clinical data on the impact of condoms on HIV transmission is exceedingly thin. In one US study of 24 discordant couples followed for a median of 24 months, among ten couples who used condoms only one partner became infected with HIV and in 14 couples who did not use condoms, 12 became infected[15]. In a study of 568 US prostitutes 11% of those reporting unprotected vaginal intercourse had HIV infection and none of 22 who said they used condoms on every episode were seropositive[16]. Another study in Denmark found that none of 101 prostitutes who claimed they used condoms on at least two-thirds of the occasions that they had vaginal intercourse had HIV infection[17].

The commonly used spermicides, nonoxynol-9 and menfegol, are detergents that dissolve the sperm surface membrane. Both substances have been shown to kill HIV *in vitro*, 60 s exposure of nonoxynol-9 at 0.05% or greater is lethal to HIV[18]. Condoms treated with nonoxynol-9 appeared effective against HIV *in vitro* even when artificially ruptured, but clinical data on spermicide use and HIV infection are lacking[19].

In 1987, FHI published the results of a study conducted with investigators in Bangkok looking at the effect of the TODAY sponge on the transmission of gonorrhea, *Chlamydia* and *Monilia* in a group of commercial sex workers[20]. Compliance in use was probably irregular. The rise in *Monilia* infection is almost certainly a reflection in the changing vaginal flora, consequent of the repeated use of the sponge which contains 1 g of nonoyxnol-9, in a group of women who had frequent sex. The same study needs to be repeated with other preparations of spermicides.

However, although spermicides kill HIV in the laboratory, and other STDs *in vivo*, caution has to be exercized in extrapolating these results to human use. Firstly, it is still not known if infection is a result of the transmission of free virus or virus in white cells, or both. Spermicides almost certainly kill white cells just as they destroy sperm, but more studies are needed in this field. More importantly, steps need to be taken to exclude the possibility that *Monilia* infection, or microtrauma associated with the use of the sponge, do not act as cofactors in HIV transmission.

Spermicides, diaphragms and condoms all reduce the risk of pelvic inflammatory disease (Table 6). Barrier methods probably reduce the risk of cervical cancer and several studies have been conducted comparing cervical pathology in barrier methods and pill users, and the most plausible explanation of the consistent differences found is that barrier methods are indeed protective.

CONCLUSIONS

Barrier methods are a common sense way of protecting against pregnancy and sexually transmitted diseases. They have not been as carefully studied

Table 6 Protection against PID

Contraceptive method	*PID rate*	*Total number of woman years of exposure (women 20–29)*
Orals	0.9	16 222
Barrier methods	1.4	7 007
Non-contraceptors	3.4	5 038

From L. Westrom (1980)[27]

as other methods of contraception and we need additional studies. However we do have sufficient information to recognize their wide usefulness – indeed for some people they are essential – and to identify what is needed to improve use.

Exposure to pregnancy is limited to 2 or 3 days in the month but as far as is known, the risk of transmitting and acquiring STDs extends throughout 365 days of the year. Clinical studies of condoms and spermicides all demonstrate a reduced risk of STD transmission but none have ever given 100% protection. However, the use of barrier methods to deter STD transmission sets up a virtuous spiral and over a relatively short time, even a moderate reduction in the risk of transmission has a marked effect on the prevalence of the disease in the community[21]. Moreover, in the case of HIV infection, concurrent STDs appear to increase the risk of acquisition (and possibly infectivity) so barrier methods may act indirectly through this process, as well as directly, as a barrier to the virus.

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