

Acceptability and Efficacy of the Female Condom : A New Barrier Method

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Introduction

With the introduction of female condoms that can be used exclusively by women at the time of intercourse, the conventional latex condom, which is worn over the penis, can now be termed as the male condom. It is expected that the female condom may find a place in the list of the most effective barrier methods by the end of this century. The condom as a barrier method serves a dual purpose - it prevents pregnancy as well as the spread of sexually transmitted diseases (STDs) including AIDS. The efficacy of the latex condom is reported to be close to 100 percent when used correctly and consistently. [1]

Women often talk about the right to choose between a pregnancy and its prevention and the right to protect themselves from STDs [2]. However, they find it almost impossible to bring up the issue of safer sex in their marital relationship and particularly when it comes to asking their husbands to use the condom as openly doubting the husband's infidelity is considered contrary to tradition. It is too confrontational or accusatory and is implied as lack of trust in her husband. Women have also expressed their anxiety that their partners have sometimes made small holes in the male condom, even through the packet, and cheated them (giving them the feeling that their partners are protecting themselves and are not concerned about protecting the woman). In this context, with the female condom, women have felt more confident because they can keep the condom, open the packets and insert it themselves and do not have to rely on their partners to use a condom. [3]

Among the potential advantages of the female condom are-its use is under the control of the woman, it may be inserted well in advance of intercourse, its loose fit may cause less loss of sensitivity and permit penetration before complete erection of the penis, it may provide greater protection against STDs (it is said to be stronger than the latex condom and hence less likely to rupture), and it permits continued intimacy in the resolution phase following intercourse. [4]

Keeping in view the advantages and the usefulness of the female condom, it seems that this may be a promising barrier method for women in the near future,

not only for preventing pregnancy but also for protecting themselves against STDs and AIDS. The present article is a comprehensive review of the acceptability and efficacy of the female condom used by women in trials conducted in different countries in the recent past.

The Device

The female condom is a polyurethane bag with outer and inner rings. It has different brand names such as Femshield, [4], [5] Reality [6], [7] and Femidom [8]. Femshield is a 15 cm. long bag with a diameter of 8 cm. The average thickness of the sheath is 0.045 mm. The diameter of the outer ring is 7 cm. It is soft but firm enough to prevent the device from disappearing into the vagina. The inner ring, which is removable is 6.5 cm and facilitates the insertion of the condom into the vagina as also prevents expulsion of the device from the vagina. [4]

Femidom is a combination of the male condom and the diaphragm. It has three new elements: (1) it is skintight like the male condom but covers the surface of the vagina allowing it to move freely inside the condom; (2) the device can be inserted before intercourse thus reducing interference with love making; and (3) it protects the entrance to the vagina (where lesions may be found), urethra as well as the base of the penis.

One study has reported many users of Femshield to express a preference for a prelubricated, seamless device which is slightly longer than its existing length; whereas, in another study, [5] a few couples have suggested that the device be modified with the bag being made smaller and thinner, the outer and inner rings reduced in size and softer, and the device itself provided in prelubricated packets. These suggestions have been carefully considered and incorporated in the female condom under the brand name, Femidom. Femidom is 17 cm. long with an outer ring of 7 cm. and an inner ring of 6 cm., and pre-lubricated with jelly containing nonoxynol-9 (a spermicide) [3], [4]. Reality, is another version of either of these two brands of the female condom.

Depending on the user's preference, the female condom may be inserted manually by the woman by compressing the inner ring of the device into the vagina in the same way as while inserting a diaphragm (the inner ring need not be positioned over the cervix, or inserted manually by her partner).

Trials

Table 1 presents a list of some of the trials conducted with different brands of female condoms during 1988-95.

Table 1 : Chronological list of some trials with the female condom

First author	Subjects	Brand	Year
Bounds	24	Femshield ^R	1988
Leeper	--	Reality ^R	1989
Drew	--	(Female condom)	1990
Gregersen	20	(Female condom)	1990
Soper	30	Reality ^R	1991
Jivasak	56	Femshield ^R	1991
Bounds	106	Femidom ^R	1992
Shervington	--	Reality ^R	1993
Soper	54	Reality ^R	1993
Trussell	--	(Female condom)	1994
Farr	328	(Female condom)	1994
Ray	196	Femidom ^R	1995

The trials were carried out to assess the acceptability of female condom, [3], [4], [11] the extent of protection and experience of current family planning users and their partners, [5] the degree of vaginal discomfort and effect on vaginal flora, [6] its durability [7] and the use-effectiveness and patient acceptability of this new barrier method. A few studies were also conducted to assess the permeability of HIV and (cytomegalovirus) through this polyurethane bag [7] and the protection offered by it against STDs and microbial infection, [10], [15]. The contraceptive acceptability and efficacy of female condom have also been tested in several studies. [13], [14]

Acceptability

Bounds and his co-workers studied 24 married or cohabiting couples who experienced 147 acts of coitus using the female condom. Fifty percent of women and 54 percent of the men found it acceptable, and 79 and 63 percent respectively reported that as compared to the male condom, sexual pleasure was neither different nor greater. Preliminary results of another acceptability study, [10] in which 20 sexually active couples who recorded 89 acts of sexual intercourse using the female condom and 21 using the male condom also gave promising results.

Among 56 Thai couples responding to a questionnaire regarding acceptability of the female condom, women more than their spouses indicated a positive attitude to the device. While initial enquiries from 106 potential volunteers revealed the

attractiveness of the female condom, the actual study of use-effectiveness and patient acceptability recorded a 56 percent drop out rate for a variety of method acceptability reasons [8]. Another study [6] with 30 women indicated that use of the female condom or the diaphragm was not associated with trauma to the lower genital tract of the women as judged by a colposcopic examination of the vagina, cervix and vulva with photographic records as also quantitative fungal, aerobic and anaerobic cultures of the vaginal flora.

A study [11] to assess the acceptance and relevance of the female condom in African-American women indicated that the cultural norms of the woman's submission and passivity in sexual negotiation was a major barrier to insistence on condom use during sexual intercourse. Ray et al [3] studied acceptability among 89 sex workers and 84 urban and 23 rural women in Zimbabwe and reported that most of the women in all three groups liked the female condom fairly well or very much, and mostly preferred it to the male condom. They also expressed 'quicker or longer to the finish' as a benefit of the female condom and its easier use-effectiveness with practice.

Women's Experiences

A study of 147 coital acts indicated that the condom was inserted by women 57 percent of the time [4]. Out of these, 12 percent of the insertions were considered difficult. In 77 percent of the cases the condom was inserted 10 minutes prior to coitus, although it can be used well in advance.

In a comparative study, [10] insertion of the female condom was generally considered easy after the first attempt. Most of the subjects found the appearance of the female condom neutral (71 percent) or the same as that of the male condom (83 percent). The colour, which was similar to the colour of the male condom, was recorded as "not good" by 9.4 percent of the women. None of the female condoms disappeared into the vagina. During limited use of the female condom, Thai women found that vaginal insertion of the device was acceptable, but the outer and the inner rings of the device caused discomfort at the time of intercourse. [5]

A clinical trial [8] with 106 volunteers also showed that the majority of the women found the female condom unacceptable and preferred its insertion prior to intercourse. Around 71 percent of the women expressed difficulty in inserting it as it was 'slippery', 'awkward', 'fiddly', 'clumsy', 'springy', 'difficult to insert high enough', 'hanging out' or 'it does not lie flat against the vagina'. However, some women did not find it difficult to insert this device. During intercourse which was on an average twice a week, 23 women found the condom slipped out of the vagina or was brought out by the penis, 34 women reported that the entire

device including the outer ring was pushed inside the vagina at least once and 26 women reported that the penis entered outside of the condom and they required to hold it by hand. In addition, 57 women reported physical discomfort. [3]

About 72 percent of the women in another study did not experience any discomfort although 39 percent of the women felt the outer ring at the time of intercourse, but considered it acceptable.

In their study, Bounds et al [4] reported a reduction of sexual pleasure during foreplay in 47 percent of the coital acts that may adversely affect woman's acceptance of this new method.

Orgasm was disturbed only to a minor degree and one of the women reported better orgasm with the female condom than without it. None reported any difficulty in removing the female condom or discomfort afterwards, while three women expressed some difficulty in removing the male condom and one experienced slight discomfort after intercourse using the male condom. The female condom was said to have no side effects and was considered superior to the male condom. [10] Thai women were more positive to it than their spouses though both reported reduced sexual satisfaction with its use.

A good proportion of African-American women enthusiastically endorsed the introduction of the female condom because they felt that it could allow them control over safer sex practices without challenging the power of their male partners. [11] In another study, the majority of the women felt happy with the female condom because it could protect them against infection as the device looked stronger and was unlikely to break, and because their partners liked it. The main complaints were related to the initial difficulties of insertion, which could be overcome with practice, that the inner ring was uncomfortable, that there was too much lubrication and that they were afraid that the outer ring might get pushed up the vagina during sexual intercourse.

Spouse's Experiences

A use-acceptability study, reported that the male partners felt the inner ring of the female condom in 62 percent of the coital acts while a pilot acceptability study [10] reported this experience, among only some male partners. On the other hand, in a clinical study of use-effectiveness and patient acceptability, 47 percent of the male partners reported greater satisfaction of sexual intercourse with the female as compared to the male condom.

In Zimbabwe, a vast majority of the male partners liked the female condom and encouraged women to get more supplies. Only a few partners of urban women

objected to the latter using the new barrier method because they thought it would encourage them to become casual about sex, or because the women would have more control and would no longer have to worry about conception or catching an infection.

Contraceptive Efficacy

Trussel et al [13] reported that the contraceptive efficacy of the condom during consistent and correct use was not significantly different from that of the diaphragm, the vaginal sponge or the cervical cap among women in USA. The six months probability of failure during consistent and correct use was 6.2 percent among US women, similar to the rate for the diaphragm and the cervical cap but significantly lower than that for the vaginal sponge. In clinical trials in USA and Latin America, [14] a total of 328 subjects who were in a mutual monogamous relationship and agreed to use female condom as their only means of contraception for six months. Among them, 22 US subjects and 17 Latin-American subjects became pregnant, yielding a six-month gross cumulative accidental pregnancy rate of 12.4 and 22.2 respectively. During consistent and correct use of the method the rates were 2.6 and 9.5 for the US and Latin-American women respectively. There were no serious adverse events related to the use of the device. The female condom provided contraceptives efficacy in the same range as other barrier methods, particularly when used consistently and correctly. [14] However, in a study of use-effectiveness, the breakage of the female condom during sexual intercourse was three percent possibly due to the presence of seams in the version-tested.

Protection Against Infection

While an initial study had shown that the female condom was less likely to leak than the male condom, subsequent tests for permeability using an artificial intercourse model could not detect any viral leakage in three separate trials each for the HIV and CMV (cytomegalovirus). [7] Also, no significant change in the population of the vaginal flora was observed during the use of the female condom. [6]

In an effort to determine if appropriate use decreases the rate of recurrent vaginal trichomoniasis, a case-control study with 104 women was carried out. The findings showed that there was no reinfection in compliant users of the female condom, whereas 14.7 percent reinfection occurred in non-compliant users during 45 days of continued sexual activity.[12] A meaningful comparison with the male condom was not possible because of the lack of data from carefully controlled perspective clinical trials. How-ever, extrapolation of results on contraceptive efficacy suggest that perfect use of the female condom might

reduce the annual risk of acquiring the HIV by more than 90 percent of the women who would have sexual intercourse twice in a week with infected males. [13]

Remarks

As a barrier method, the mechanism of action of the male and female condoms for prevention of pregnancy and protection against infection is similar. In an ideal condition, the condom may prove to be a 100 percent effective measure against conception and transmission of infection. However, the environmental setting, behaviour of partners, incorrect use, lubrication and brand of condom may contribute to its failure. Studies [15] carried out in Ghana, Kenya, Mali, Mexico, Nepal, Sri Lanka and USA indicate a breakage rate during vaginal intercourse using lubricated latex condoms in the range of 0.6 percent for all condoms used in Sri Lanka to 13.3 percent in Ghana. Most of these studies reported a breakage rate below five percent. The slippage rate was as high as 9.3 percent in Kenya and less than four percent in other countries. When breakage and slippage were combined, the total condom failure rate ranged from 3.8 to 13.3 percent. [15] Similar findings have been reported by other workers. [16], [17] A much lower breakage rate of the male condom in a study [10] of commercial sex workers (anal intercourse: 0.5 percent; vaginal intercourse: 0.8 percent) has been attributed to the presumptive nature of the survey and its documentation, use of good quality fresh condoms, the experience of the users, and that commercial sex usually lasts for a shorter time than amateur sex and thus puts less stress on the condom. The latex condom has also been reported to visibly deteriorate with prolonged vaginal intercourse. [18]

A prospective study [19] using two brands of the male condom found that out of 405 condoms, 7.9 percent either broke during intercourse or withdrawal, or slipped off. None of these events were observed to be related to the brand of the condom, past condom use, or use of additional lubricant. Of the remaining 7.2 percent that slipped off during withdrawal, the slippage was unrelated to the brand of the condom but was significant when additional lubricants were used. Steiner and his coworkers [20] obtained a breakage rate ranging from 3.5 percent for a condom from a brand new lot to 18.6 percent for a condom from a lot that was 81 months old. The most unexpected finding was that the age of the male condom lot was the least predictor of condom breakage during use. In the case of the female condom, a three- percent breakage rate during sexual intercourse has been reported. These results show that consistent and correct use of the device - whether the male or female condom - and behaviour of the partners during sexual activity seem to be the most important factors for attaining the highest efficacy of the device.

The contraceptive efficacy of the female condom when used consistently and correctly is not significantly different from that of other barrier methods. [13] The contraceptive failure rate of the male condom varies from two to 13 percent depending on the study populations, yet it is the contraceptive method with the greatest capacity to protect against sexually transmitted diseases and AIDS. [21] The same may be true for the female condom. Moreover, it has another important advantage that its use is controlled by the woman herself. In a situation wherein sex workers were forced at one time or another to have unprotected sex because their clients adamantly refused to wear the (male) condom, they agreed that the female condom gave them an alternative which they could insert themselves though most of the time they still needed their partners' consent. Nevertheless, whether it is used in a sustained and consistent manner so that it is effective over a longer potential period as a barrier to STDs and HIV, depends on its availability, affordability, perception of personal risk and ongoing insistence on and belief in protection of self and others.

Nonoxynol-9 which is often used along with the female condom as a lubricant appears to have a protective effect against some STDs. The data concerning the protective effect of spermicides containing nonoxynol-9 against HIV is conflicting, yet suggests some protection especially if the products are used with relatively low frequency that avoid dose-dependent vaginal irritation. Currently, spermicides which could also protect against viral infection without affecting epithelial cells are being studied. [21] Although encouragement of condom use is prudent on an epidemiological scale, truly safe sex with an HIV positive partner using a condom is a dangerous illusion. [17]

The acceptability of the female condom requires negotiation between men and women. A major barrier to negotiating safer sex is the communication gap between partners. Studies with the female condom show that it is not inferior to any other barrier method in terms of contraceptive efficacy and prevention of transmission of STDs and AIDS and at the same time, there is no adverse effect. Therefore, if abundant supplies of the female condom are made available along with the male condom, it is likely that a section of the population may accept it as an alternative to the male condom.

In a study conducted by Ray et al, [3] 74 percent of urban women and all the rural women interviewed said that their steady partners liked the female condom. Among sex workers, 92 percent said that their steady partners liked the female condom and 77 percent found that their random clients also liked it. One of the problems of using female condom, as expressed by some is too much lubrication in the context of the wide-spread use of vaginal drying agents prior to engaging in sexual intercourse. Such practice may affect condom use. However, changing men's and women's attitudes towards drying agents may be necessary if the

female condom is to be accepted and used effectively by some groups. Such attitudes may also influence acceptance of promising anti-HIV agents such as the lubricants because of the demand for dry sex.

When fertility control is reduced to the technical provision and use of methods without affecting sexuality and sexual practices, it lets people off from facing the deeper issues. Thus change is limited and the status quo is less threatened or not threatened at all. [2] Therefore, the acceptance of the female condom requires dissociation from gender bias because the willingness and active cooperation of both partners is necessary to optimise its acceptability and effectiveness as a barrier method. Some women opined that even though the female condom did not interfere with the woman's sexual pleasure, most of the reasons for liking it were male centred. [3] At the same time, the female condom needs to be cheaper and more widely available everywhere, because women need all the help they can get. From a woman-centred point of view, however, it is also important to insist on male condoms and men being involved so as to begin to get to the root of the gender problem and not just deal with its consequences. [2]

Conclusions

As a barrier method, the female condom has an efficacy and failure rate similar to that of any other currently available barrier method. It has no adverse effects and can be used by women as and when they need to. Therefore, the female condom can be a very effective method to cope with the need and exigencies of the modern lifestyles as also for preventing the transmission of STDs and HIV.

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