Contraceptive Efficacy and Acceptability of the Female Condom

ABSTRACT

Objectives. The purpose of the study was to determine the contraceptive efficacy of the female condom and to provide data about the device to the US Food and Drug Administration.

Methods. The clinical trial was conducted at six US sites and three sites in Latin America. Eligible subjects were in mutually monogamous relationships and agreed to use the female condom as their only means of contraception for 6 months.

Results. A total of 328 subjects contributed to the analysis of contraceptive efficacy. Twenty-two US subjects and 17 Latin American subjects became pregnant, yielding 6-month gross cumulative accidental pregnancy rates of 12.4 and 22.2, respectively. During perfect (consistent and correct) use of the method, the 6-month accidental pregnancy rates were 2.6 and 9.5 for the US and Latin American centers, respectively. There were no serious adverse events related to the use of the method.

Conclusions. The female condom provides contraceptive efficacy in the same range as other barrier methods, particularly when used consistently and correctly, and has the added advantage of helping protect against sexually transmitted diseases. (*Am J Public Health.* 1994;84:1960–1964)

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Introduction

The female condom is an innovative barrier contraceptive that also offers potential protection against sexually transmitted diseases. Although the idea of a female condom is not new, early designs did not become widely available.[1,2] More recently, a device made of a lighter and stronger material, polyurethane, has been developed (Reality Female Condom, Wisconsin Pharmacal).

The new female condom consists of a soft, loose-fitting sheath and two flexible polyurethane rings. One ring lies inside the vagina at the closed end of the sheath and serves as an insertion mechanism and internal anchor. The outer ring forms the external edge of the device and remains outside the vagina after insertion, thus providing protection to the labia and the base of the penis during intercourse. The condom is prelubricated and is currently intended for one-time use only. Fitting by a health professional is not required. The polyurethane material used in this device is stronger and has been found to be less prone to rupture than latex rubber, can be used with a variety of lubricants, and has not been shown to be susceptible to deterioration under less than ideal storage conditions.[3]

In 1990, Family Health International and the Contraceptive Research and Development Program, with funding from the US Agency for International Development, initiated a clinical trial of the Reality female condom to test the contraceptive efficacy of the device. The study was a 6-month Phase II noncomparative multicenter clinical trial in which the design reflected the then-current draft guidelines from the US Food and Drug Administration for testing female barrier methods also intended to reduce the risk of sexually transmitted diseases. This paper reports the results of this 6-month trial.

Methods and Materials

A total of 377 subjects were enrolled at nine sites, six in the United States (n = 262) and three in Latin America (two in Mexico and one in the Dominican Republic, n = 115). Subjects were to be followed for a period of 6 months so that a minimum of 1200 woman-months of experience could be collected. Potential subjects were recruited through advertisements or were volunteers from the general population of clients attending the nine participating study clinics for family planning services.

Screening and Admission Procedures

Women were eligible for the study if they were between 18 and 40 years of age, were in an ongoing mutually monogamous heterosexual relationship, were willing to use the female condom as their only means of contraception for 6 months, and had had at least two normal menses since their last pregnancy (if ever pregnant) or since terminating hormonal contraception. Women were excluded from the study if they had clinical evidence of pelvic inflammatory disease, were currently preg-

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nant (as confirmed by urine pregnancy test), desired pregnancy within the next 6 months, had ever been allergic to vaginal lubricants, had evidence of past toxic shock syndrome, were breast-feeding an infant, had a Class III or higher Pap smear, had clinical evidence of current urinary tract infection or a history of two or more episodes per year, had symptoms of a sexually transmitted disease, or had contraindications to pregnancy.

Eligible women were enrolled in the trial pending the results of Pap smears and pregnancy tests. Enrolled subjects were provided with a booklet giving instructions on the use of the device and a coital log, given a supply of female condoms and extra lubricant, and told to return to the clinic for regularly scheduled follow-up visits. They were also instructed to contact the clinic if their menstrual period was overdue or if they experienced any medical problems. Women were discontinued from further follow-up if the results of their admission pregnancy tests were positive or if their Pap smears were Class III or higher.

TABLE 1—Baseline Characteristics of the Intent-to-Treat Population[a]

	United States (n = 262)	Latin America (n = 115)
Mean age, y	28.9	26.4
Mean education, y	14.4	9.7
Primary contraceptive method during 3 mo prior to admission, %		
None	6.5	8.7
Male condom	48.1	40.0
Diaphragm/cervical cap/sponge	13.4	0.0
Rhythm/withdrawal	9.2	7.8
IUD	0.4	25.2
Oral pill	5.0	7.8
Combination or other	17.5	10.5
Previous experience with barrier contraceptives, %		
None	3.4	31.3
Used only a few times	6.9	13.0
Used occasionally	20.2	20.9
Used often	69.5	34.8
Mean no. of acts of intercourse per month	12.9	12.5
Parity, %		
Nulliparous	39.7	1.7
Parous	60.3	98.3
Mean no. of live births	1.0	2.0

[a]The Intent-to-Treat population (n = 377) consisted of all eligible volunteers recruited for the study.

Follow-Up Procedures

The subjects were followed up at 1, 3, and 6 months after admission. At each follow-up visit, a pelvic examination was performed, the coital log and product use history were recorded, and additional supplies were provided. At month 6, each woman had a Pap smear and a urine pregnancy test. In addition, each woman was asked to return 2 weeks after the month 6 or earlier discontinuation visit for a final urine pregnancy test to rule out any pregnancies missed at these final visits. Subjects were asked to complete an open-ended questionnaire at the study completion or early discontinuation visit.

Reasons for discontinuation were grouped into the following categories: accidental pregnancy, medical reasons, personal reasons (including low coital frequency), planning pregnancy, or lost to follow-up. A suspicion or clinical diagnosis of pregnancy was confirmed with a urine pregnancy test.

Statistical Analysis

Demographic characteristics were collected and the baseline data summarized for all women enrolled in the trial (Intent-to-Treat population, n = 377). In accordance with the general policies of the Food and Drug Administration, the safety analysis used data from all women (including those with protocol deviations) who were given the female condom and who returned for at least one postadmission follow-up visit (Treated population, n = 359). The analysis of contraceptive efficacy focused on the subset of women in the Treated population who met the protocol inclusion criteria and who used the female condom at least once (Efficacy population, n = 328).

Gross cumulative life-table rates were used to assess accidental pregnancy and termination for specific reasons, independent of all other reasons.[4] Subjects who fell below the coital frequency requirements stated in the protocol (an average of less than four acts per month) were censored from the life-table analysis just prior to the violation.

Perfect-use pregnancy rates were also calculated to determine the female condom's effectiveness among women who used the product consistently and correctly. Perfect-use intervals were defined as periods between two follow-up visits in which subjects reported using the female condom at every act of intercourse, did not use other methods of contraception, and used the female condom according to instructions. In addition, intervals were considered perfect only if the subject reported having engaged in at least four acts of intercourse during the month preceding the follow-up visit. Life-table estimates of perfect-use rates were calculated by including all months of follow-up for each eligible woman until the beginning of the first interval of imperfect use. For example, if a subject reported perfect use from admission through her month 3 visit, but reported imperfect use between her month 3 and month 6 visits, only data from admission through month 3 were included in the analysis. Therefore, any pregnancy that occurred prior to the first interval of imperfect use contributed to these rates.

Results

Data for pooled US centers and pooled Latin American centers are presented for all results. A comparison of the baseline characteristics across US and Latin American centers did not support combining the data.

Demographics and Reproductive History

Sociodemographic characteristics and reproductive history for the 377 women in the Intent-to-Treat group are presented in Table 1. There were differences between the US and Latin American subgroups in terms of age, education, parity, contraceptive use immediately preceding study enrollment, and previous experi-

TABLE 2—Status at End of Study for Subjects in the Efficacy Population[a]

	US Subgroup (n = 221)		Latin American Subgroup (n = 107)	
	No.	%	No.	%
Completed study	147	66.5	48	44.9
Discontinued participation				
Personal reasons	42	19.0	31	29.0
Accidental pregnancy	22	10.0	17	15.9
Medical reasons	4	1.8	3	2.8
Planned pregnancy	1	0.4	4	3.7
Lost to follow-up	5	2.3	4	3.7
Total	74	33.5	59	55.1
Returned for 6-month follow-up	153	69.2	54	50.5

[a]Subjects in the Efficacy population (n = 328) were those who met inclusion criteria and had at least one follow-up visit and one use of the female condom.

TABLE 3—Gross Cumulative 6-Month Life-Table Rates of Discontinuation for the Efficacy Population (n = 328)

Reason for Discontinuation	US Subgroup (n = 221)		Latin American Subgroup (n = 107)	
	Rate[a]	SE	Rate[a]	SE
Accidental pregnancy	12.4	2.55	22.2	5.34
Personal reasons	21.0	2.99	33.4	5.61
Planned pregnancy	0.5	0.58	6.4	3.44
Medical reasons	2.5	1.28	3.8	2.74
Lost to follow-up	2.5	1.29	6.0	3.35
Total discontinuation[b]	34.5	3.18	56.2	4.79

[a]Per 100 women.
[b]Discontinuation for any of the reasons listed above.

ence with barrier contraceptives. Of particular note, more women in the Latin American group (31.3%) than in the US group (3.4%) had had no previous experience with barrier methods. In addition, more women overall in the US group (61.5%) than in the Latin American group (40.0%) were using barrier contraceptives (condom, diaphragm, cervical cap, or sponge) as their primary method in the 3 months immediately preceding study enrollment. Substantially more women in the US group (39.7%) than in the Latin American group (1.7%) were nulliparous.

Discontinuation and Efficacy Analyses

Table 2 presents study completion status for the Efficacy population. More women in the Latin American group (55.1%) than in the US group (33.5%) discontinued participation in the study. Personal reasons accounted for over half the discontinuations in both groups. Table 3 presents 6-month gross cumulative life-table discontinuation rates (per 100 women) by reason. Overall, discontinuation rates were lower among US women than among Latin American women for each of the five reasons reported. In both groups, the highest discontinuation rates were observed for accidental pregnancy and personal reasons (e.g., subject moved, subject or partner did not like device, subject no longer had a partner).

The 6-month gross cumulative pregnancy rates were 12.4 and 22.2 for the US and Latin American groups, respectively. Twelve of the 39 pregnancies reported during the study were classified by the investigators as method failures (6 were due to mechanical or structural failure of the device, such as breakage; 6 were unexplained but the investigator found no indications of user failure). Twenty-four pregnancies were classified as user failures, and 3 were classified as "other" failures (the investigator could not determine whether the pregnancy was due to user or method failure).

Sufficient data were collected on all but one of the women in the Efficacy population to assess compliance. Approximately two thirds of the women in both groups reported noncompliance with product use instructions or the protocol at some time during the study (Table 4). The main reasons included failure to use the female condom at every act of intercourse (about 60% in each group) and use of another contraceptive product (about one third in each group). Reasons for irregular use differed between the US and Latin American groups. The main reasons in the US group were unavailable supplies, menses, subject found the method troublesome, and "other"; the main reasons in the Latin American group were subject neglect, partner objection, and discomfort.

Approximately 60% of the women in both subgroups contributed one or more intervals to the perfect-use analysis. The 6-month gross cumulative life-table perfect-use pregnancy rate was 2.6 for the US subgroup and 9.5 for the Latin American subgroup (Table 5).

Safety

Most of the medical problems or conditions reported during the study were in the US group and were not considered related to use of the device (e.g., injuries suffered in automobile accident, mass on left ovary, urinary tract infection, myalgia paresthesia). Although one case of pelvic inflammatory disease was reported during the study, there were no serious, life-threatening adverse events related to use of the female condom.

Vaginal irritation possibly caused by the product and changes in Pap smears were carefully evaluated. A total of 269 women had Pap smears taken during follow-up. (A Pap smear was taken at each woman's end-of-study visit or any time one was warranted, although a smear was not routinely performed when a pregnancy was diagnosed.) A majority (83.8%) of the US subgroup had normal Pap smear results at both admission and follow-up, whereas a majority (57%) in the Latin American subgroup had atypical results at both admission and follow-up (data not shown). There appeared to be no negative changes associated with use of the female condom.

TABLE 4—Use of the Female Condom and Protocol Compliance in the Efficacy Population (n = 328)

	US Subgroup (n = 221)		Latin American Subgroup (n = 106)	
	No.	%	No.	%
Compliance status				
Compliant	85	38.5	32	30.2
Noncompliant[a]	136	61.5	74	69.8
Used device at every act of intercourse				
Yes	95	43.0	40	37.7
No	126	57.0	66	62.3
Reason for irregular use[b]				
Condom unavailable at time of intercourse	41	25.0	9	11.8
Patient neglect	15	9.1	20	26.3
Partner objection	13	7.9	18	23.7
Physical discomfort (either partner)	8	4.9	19	25.0
Subject having menses	26	15.9	0	0.0
Device too troublesome	18	11.0	1	1.3
Subject did not like device	11	6.7	1	1.3
Other	32	19.5	8	10.5
Used other contraceptives[c]	79	35.9	34	32.1
Used product according to instructions[d]	195	89.9	94	88.7
Reported fewer than four acts of intercourse[e]	11	5.2	8	7.5

[a]Subjects were classified as noncompliant if they ever reported irregular use of the study product, ever used another method of contraception, did not use the study product according to instructions, or had fewer than four acts of intercourse during the month preceding a follow-up visit.
[b]More than one reason could be given.
[c]Data were missing for 1 subject; therefore, US n = 220 for this item.
[d]Data were missing for 4 subjects; therefore, US n = 217 for this item.
[e]Data were missing for 8 subjects; therefore, US n = 213 for this item.

TABLE 5—Gross Cumulative Life-Table Pregnancy Rates during Perfect Use of the Female Condom

	US Subgroup (n = 135)		Latin American Subgroup (n = 66)	
	Rate[a]	SE	Rate[a]	SE
Month 1	1.6	1.20	1.6	1.63
Month 3	2.6	1.74	1.6	2.13
Month 6	2.6	2.66	9.5	6.76

Note. Subjects were included in the perfect-use analysis until their first report of imperfect use. Imperfect use is defined as irregular use of the device during intercourse, use of another method of contraception, failure to use the device according to instructions, or having fewer than four acts of intercourse during the month preceding a follow-up visit.
[a]Rates are per 100 women.

Acceptability

Acceptability data were gathered via a self-administered questionnaire at the end of the study or at the time of discontinuation. More than 80% of all subjects who completed questionnaires reported that they liked using the female condom and would recommend it to others. Many women indicated that they would like to use it as their method of contraception in the future (about 45% in the US subgroup and about 62% in the Latin American subgroup). Product-related complaints included dislike of the inner ring, "didn't feel right," inconvenience, and messiness. Some women said their male partners did not like the device and a few women said this was the reason they were sometimes noncompliant; a few women gave this reason for discontinuation from the study. A detailed analysis of the acceptability data from this study will be presented elsewhere.

Discussion

Studies have shown that the female condom is impermeable to sperm, sexually transmitted disease pathogens, and the human immunodeficiency virus.[3] However, the success of any compliance-based contraceptive method, as well as the ability of the device to serve as an effective barrier during penetrative intercourse,[1] requires correct and consistent use. Therefore, it is important to distinguish between "perfect" and "imperfect" use when evaluating pregnancy rates for a given barrier method. Assessing perfect-use rates is important because it gives users information on how well the device can work when used according to directions (Dominik R, Trussell J, Walsh T, unpublished manuscript).[5,6] In this study, perfect-use rates were substantially lower than overall pregnancy rates, particularly in the US subgroup, indicating that the female condom can be a highly effective method when used consistently and correctly. Noncompliance was due mostly to factors such as partner objection, occasional negligence, and discomfort when using the device. It is not clear why the perfect-use rates of the US and Latin American subgroups were so different. However, the estimate for the Latin American subgroup is very imprecise, as indicated by the high standard error (Table 5).

Acceptability of the female condom was quite good in this study. Product-related complaints were generally limited to the uniqueness of the device (e.g., dislike of the inner ring) or to aspects common to other barrier methods (e.g., inconvenience, messiness). Objections to use of the device by the male partner affected reported acceptability and consistent use of the product more in the Latin American subgroup than in the US subgroup. Nevertheless, most of the women indicated that they liked using the device, would recommend it to others, and would select it above other barrier methods in the future.

New medical problems or conditions reported during the study were generally transient. There were no reports of sexually transmitted diseases or serious, unexpected, or life-threatening adverse experiences related to use of the female condom. There was also no evidence that using the female condom increased the risk of cervical changes.

Because this clinical trial was noncomparative, it is not possible to make any absolute statements about how the device compares with other barrier methods. However, the overall use-effectiveness that we observed in the US subgroup is within the range of rates reported for US women using the cervical cap, the contraceptive sponge, and the diaphragm with spermicide.[7] Several factors probably bias the pregnancy rates for the female condom upward compared with these historical rates, in particular the fact that in this study, all pregnancies, including chemical pregnancies (those diagnosed only by urine pregnancy tests) that led to spontaneous abortion, were counted in the failure rates and couples with low coital frequency were excluded from the analysis.[7]

In theory, female condoms offer many potential advantages over male condoms.[1-3] The female condom can be inserted in advance of sexual activity and, as a result, should allow more sexual spontaneity. Couples could engage in sexual intercourse before full erection of the penis. Because of its design, the female condom covers both the internal and external genitalia, thereby providing greater protection against sexually transmitted diseases.[3] The female condom does not need to be removed immediately after ejaculation, providing for greater intimacy after intercourse (with the male condom, the potential for the condom's slipping off a flaccid penis is great). Finally, the female condom is made of stronger material (polyurethane) than latex condoms and is therefore less likely to rupture or to have the pinholes common in natural latex condoms.[3]

Although the pregnancy failure rates established in this trial suggest that the female condom can provide protection against sexually transmitted diseases, further study is needed to accurately measure the prophylactic potential of this method. Because of the acceptability and effectiveness of this device, it may play an important role in the prevention of unwanted pregnancy and sexually transmitted diseases. □

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