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Hiv Antiretroviral-Based Intravaginal Rings with and Without Co-Formulated Contraception Hold Promise for Increasing Hiv Prevention Options for Women

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Abstract

An integrated sexual and reproductive health approach, with emphasis on multipurpose prevention technologies (MPTs), is believed to offer the best solution for addressing women's needs . Among the multiple MPTs under development, intravaginal rings (IVRs) have tremendous potential for preventing pregnancy, HIV, and other sexually transmitted infections (STIs) . Only two IVRs are licensed for contraceptive use, neither of which are available currently in Kenya. Acceptance of and ability to correctly and consistently use IVRs in this setting are largely unknown.

Keywords: Women; reproductive health; contraceptive intravaginal ring; biomedical technology; sexual behavior; pregnancy; HIV and STI prevalence

Introduction

An integrated sexual and reproductive health approach, with emphasis on multipurpose prevention technologies (MPTs), is believed to offer the best solution for addressing women's needs [1]. Among the multiple MPTs under development, intravaginal rings (IVRs) have tremendous potential for preventing pregnancy, HIV, and other sexually transmitted infections (STIs) [2]. Only two IVRs are licensed for contraceptive use, neither of which are available currently in Kenya. Acceptance of and ability to correctly and consistently use IVRs in this setting are largely unknown.

Vaginal delivery of hormonal contraceptives and antimicrobials avoids the need for diurnal administration, circumvents systemic immersion, limits needed boluses by avoiding hepatic first- pass metabolism, and can be used by women discreetly(3). Correct and harmonious IVR use, still, may be hovered by complex artistic, behavioral, physiological, physical, interpersonal, and structural issues that may not be honored or are conceded but played down during clinical development(4- 6). similar factors include, but aren't limited to, sexual practices, intravaginal hygiene and period practices, side effect enterprises or gests , amenability to expose use to others, reproductive intentions, mate support, vaginal comfort, hindrance during intercourse, hormonal side goods(nausea, headaches, gastrointestinal symptoms, vaginal discharge), the ring getting lost in the body(7- 10), and IVR parcels(e.g., system of insertion, duration of use, color, smell, size)(11).

Studies of NuvaRing, a one- month, low- cure etonogestrel and ethinyl estradiol- grounded ring, and other IVRs in development have suggested high product adequacy(- 14) with stoner satisfaction centered on a woman being suitable to control ring insertion and junking, absence of flashing back to take a diurnal lozenge, and comfort and ease of use(15).

A abecedarian question in introducing MPT IVR is whether women in developing countries are interested in such a product and its intended use(s). In this paper, we examined factors associated with enrolling in a study of NuvaRing use and describe ideational adequacy of a contraceptive IVR(i.e., amenability to use a product solely grounded on information entered about it).

Material and styles

Design

Between April and November 2014, we enrolled women in a single group experimental study of NuvaRing. Our exploration design included apre-product phase ranging from 1 to 3 months(grounded on oral or injectable contraceptive use at registration) that was followed by 6 months of NuvaRing use, a one monthpost-product phase during which women returned to oral, injectable, or another contraceptive system of their choice, and also exited the study. For this analysis, we concentrated simply on screening data.

A multidisciplinary platoon of babe, data collectors, HIV test counselors, and study clinicians culturally analogous to the target population and fluent in the three languages primarily spoken in the area(i.e., English, Kiswahili, and Dholuo) oversaw perpetration of the study. All pelvic examinations were performed by womanish clinicians.

Ethical review

Review and blessing of the study protocol, concurrence forms, and data collection instruments was completed by the Scientific Steering and Ethical Review panels of the Kenya Medical Research Institute, and an Institutional Review Board for the United States(US) Centers for Disease Control and Prevention. This trial is registeredwithClinicalTrials.gov numberNCT02529683.

Written informed concurrence was completed by women in their language preference before sharing in data and instance collections. Women who completed the in- depth webbing process entered a bar of cleaner, 500 Kenya Shillings(roughly$ 5 US bones) for transport, womanlike aseptic pads, and a treated malaria bed net. No impulses were handed for thepre-screening eligibility assessment conducted in the reclamation venues.

Using convenience slice, women were signed from family planning and reproductive health conventions, via 10 community health workers, and party word- of- mouth referrals without impulses. Grounded on original community feedback, an overview of the study was presented to women in groups as opposed to approaching women collectively. Women entered information on the study, its purpose, and the pitfalls and benefits of an IVR. They were shown a sample of the ring, allowed to visually and manually check it, and a 3-dimensional womanish reproductive model was used to demonstrate ring insertion and junking.

Eligibility and data collection

A two- step webbing process(pre-screening and webbing) was used.

After intimately carryingpre-screening written informed concurrence and being assigned a unique study identification number, reclamation staff administered a briefpre-screening computer- supported particular interview(CAPI). A woman was eligible to do with webbing if she was 18 to 34 times of age, lived within 150 kilometers of Kisumu City, was sexually active in the once three months on further than one occasion, had used injectable depot medroxy- progesterone acetate(DMPA) or oral contraceptive capsules(OCPs) in the once three months, and had noway entered an HIV-positive test result. Women also had to report amenability to switch from their being birth control system to using NuvaRing for six months, to suffer periodic pelvic examinations and testing for gestation, HIV and other STIs, and to give family clinic attestation of DMAP or OCP use in the once 3 months, as well as standard public attestation of age(e.g., identify card, birth announcement/ instrument).

Eligible women listed for a clinic webbing visit, in which they presented the forenamed documents and completed a alternate, more comprehensive written-informed concurrence that covered study pitfalls, benefits, party conditions, and procedures specifically related to webbing and thepre-product phase. Detailed contact information was gathered and demographic, psychosocial, and behavioral information collected using audio computer- supported tone interview(ACASI). A womanish 3- dimensional reproductive model was used to describe and demonstrate what would be during the pelvic examination, and enterprises were addressed before initiating the examination. Venous blood, urine, slaver and cervicovaginal lavage instance collection was accepted to test for gestation, HIV, herpes simplex contagion type 2(HSV- 2), gonorrhea, syphilis, chlamydia, and bacterial vaginosis(BV). Verification that there were nopre-existing reproductive tract conditions was done through hematological and biochemistry analysis(e.g., cervical cancer visual examination webbing was completed using acetic acid and Lugol's iodine). Rapid HIV testing was performed with pre- and post- test comforting and results handed according to Kenyan Ministry of Health guidelines(16). Women were encouraged but not needed to expose implicit study participation to sexual mates.

A follow- up appointment was made within two weeks of the webbing visit to permit clinical staff to review laboratory results and make a final study eligibility determination. Women weren't eligible to share if they were set up to have current or a history of given medical contraindications for NuvaRing use(e.g., thrombophlebitis or thromboembolic diseases, cerebral vascular or coronary roadway complaint, valvular heart complaint with thrombogenic complications, severe hypertension, diabetes with vascular involvement, headaches with focal neurological symptoms), to be suckling or within three months of labor, or tested positive for HIV. Women who tested HIV positive were handed fresh comforting, passed CD4 and viral cargo testing, and appertained to a patient support center for applicable HIV care and treatment services. Women who tested positive for gonorrhea, syphilis, or chlamydia were handed treatment and encouraged to invite their sexual mates to come for STI operation and treatment(16). Eligible women who declined study participation were asked to complete a turndown CAPI questionnaire.

Measures

Registration status(1 = enrolled, 0 = not enrolled) was our outgrowth. ACASI demographic variables included age group, ethnical/ ethnical group, connubial status, religion, loftiest position of education completed, employment status, main source of income, and number of children in the ménage.

ideational adequacy, with dichotomous scores(1 = yes, 0 = no), was grounded on the CAPIpre-screening question, Are you willing to change from to using a vaginal ring to avoid or delay gestation? ideational adequacy was viewed aspre-product use acceptance given that factual product use would be accepted 1- 3 months post registration as opposed to academic amenability, in which intentionality may not be specific to a particular product(brand or expression) or future timeframe. ideational adequacy was operationalized as amenability to use NuvaRing after entering detailing information about it, being given the occasion to visually and manually check the ring, and being shown how it was fitted and removed using a 3- dimensional womanish reproductive model.

Psychosocial variables, with dichotomous scores(1 = yes, 0 = no), were grounded on questions on provocations for participation, gestation intentions solicitations, contraception use walls, and amenability to suffer periodic testing for gestation, HIV, and other STIs. Pelvic test acceptance particulars espoused from Fiddes and associates(17) were rated on a 5- point Likert scale(1 = explosively agree, 2 = agree, 3 = undecided, 4 = differ, and 5 = explosively differ) and a party- position mean score was generated. The response scale for four negatively articulated particulars(find pelvic test unwelcome but can tolerate, anxious about the pelvic test, worried about the pelvic test, would refuse the pelvic test if offered) was reversed before scoring. Advanced mean scores indicated less acceptance of/ lesser concern about pelvic examinations. Cut- points for pelvic test acceptance orders were deduced from the quartiles for the pelvic test measure(mean = 2.8 and standard = 3.0; minimum = 0.7 and outside = 4.5; lower quartile = 2.7 and upper quartile = 3.0). Three acceptance cut- points(mean score ≤2.7 = high acceptance, mean score2.7-2.99 = medium acceptance, and mean score ≥ 3 = low acceptance) were established.

Behavioral variables were age at sexual debut, number of coitus mates(continuance and in the once 3 months), history of forced coitus, HIV-positive mate in the once 3 months, mate of unknown HIV status in the once 3 months, exchange coitus in the once 3 months, vaginal or anal coitus in without a condom in the once 3 months, history of having coitus during monthlies, past history of STI opinion, alcohol use in the once 30 days, ever used medicines for recreational purposes, abnormal vaginal bleeding in the once 12 months, and once drug- taking history. Laboratory results for gestation, HIV, and STIs were also included.

Statistical analysis

We reckoned frequence counts and probabilities to describe the demographics, psychosocial, and behavioral characteristics of women screened. In a univariable analysis, we compared registration status across groups of categorical predictors using frequence rates attained from a log- binomial retrogression model. Acclimated effect estimates with 95 robust confidence intervals were attained in a multivariable Poisson retrogression using the generalized estimating equations(GEE) approach. We employed backward elimination procedure with a0.2 threshold position to elect covariates in multivariable retrogression. All analyses were performed in SAS9.3(SAS InstituteInc., Cary, NC, USA).

Results

Pre-screeners

Among the 692 womenpre-screened, 634(91.6) were set up to be eligible to continue with the in- depth webbing. roughly 97 ofpre-screened women were willing to switch from their current contraceptive system to NuvaRing for six months. The three most common reasons forpre-screening ineligibility were disinclination to switch to NuvaRing, not engaged in> 1 occasion of vaginal intercourse on different days in the once 30 days, and tone- reported positive HIV status. Among the eligiblepre-screened women,26.9 were screening visit no- shows. Duringre-contact attempts, some women told babe that they were concerned about mate support, discovery of the ring during sexual intercourse, and pain or discomfort associated with pelvic examinations.

Screeners

Out of 463(73.0) women who completed the webbing visit, three declined farther study consideration. After meeting all eligibility criteria, 302(99.3) of 304 women were enrolled into thepre-product phase of the study. Among women not eligible to take part in the study, reasons included testing positive for HIV(67/39.1), lack of OCP/ DMPA attestation(39/22.8), body mass indicator>29.0(34/19.9), presently suckling or within three months of labor(9/5.3), and laboratory verified gestation(8/4.7). Among enrollees, 54(17.9) were OCPs druggies and 248(82.1) were DMPA druggies.

Roughly 63 reported being employed reported payment- predicated earnings as a main source of income had a primary education or lower were Roman unqualified, and67.9 were married or cohabitating. The mean number of live births was2.5(standard2.0; range 0- 8) with roughly 45 reporting that they had three or further live births.

In the bivariate analysis, women who did not report free medical care for STIs as a motivator were less likely to be enrolled(frequency rate(PR) = 0.84, 95 confidence interval(CI) = 0.73-0.97) than those enrolled. Women who reported wanting to learn how to avoid HIV trouble conduct as a motivator were less likely to be enrolled(PR0.85, 95CI0.73-0.99) than those enrolled. Anyhow of enrollment status, entering impulses was the least common motivator overall, with 31 of women screened reporting that they were interested in joining the study for this reason.

Overall, lower than 10 reported that they had asked or wanted to get

pregnant within the coming 12 months7.0 indicated that they wanted to be pregnant in the coming 12 months and9.6 planned to get pregnant in the coming 12 months. Slightly over 13 responded that their mate wanted them to get pregnant in the coming 12 months. numerous walls to using modern contraceptives were linked. walls predominately centered on enterprises regarding access(17.6), affordability(15.5), and side goods(15.0). No significant difference in acceptance of pelvic examinations was observed between women enrolled and women not enrolled. Overall scored medium acceptance of pelvic examinations.

Overall, frequency was1.7 for gravidity for HIV, and70.4 for other STIs. Sexual debut before the age of 17 was reported by54.8. While no statistical differences were observed between those enrolled and not enrolled of women screened reported passing physically forced commerce at some point in their lives. Women who reported a single continuance sexual mate(PR1.34, 95CI1.07-1.67) or those reporting 2- 3 continuance sexual mates(PR = 1.23, 95 CI1.02- 1. 59) were more likely to be enrolled than those who reported four or further continuance mates Women who reported a single sexual mate in the formerly three months(PR1.42, 95CI1.07-1.88) were more likely to be enrolled than those who reported two or further sexual mates in the formerly 3 months. While data were collected singly for vaginal and anal commerce in the formerly 12 months, we combined these variables given that the frequency for anal intercourse in the formerly 12 months for all women who completed the netting ACASI was7.3. Apropos, 33 out of 34 women reporting anal intercourse in the formerly 12 months reported that condoms were not used. Overall engaged in vaginal or anal commerce without a condom in the formerly three months. Women using DMPA in the formerly 12 months were more likely to be enrolled(PR = 1.36, 95CI1.09-1.69).

In the multivariable model, enrollment was significantly($p<0.05$) more likely among women who were progressed 18- 24 times old, wedded/ cohabitating, reported sexual debut at lower than 17 times of age, had one continuance sexual mate, abnormal vaginal bleeding in the formerly 12 months, vaginal or anal commerce without a condom in the formerly three months, and did not have a sexual mate of unknown HIV status in the formerly three months. DMPA use in the formerly 12 months was not significant in the multivariable model.

Discussion

This study successfully inked and enrolled women for thepre- product use phase of a contraceptive IVR study in Kisumu, Kenya. roughly for every five womenpre- screened, two were enrolled in our study. Multivariable regression analysis showed that enrollment was significantly advanced among women who were lower than 25 times of age, reported a single continuance sexual mate, did not have a recent mate of unknown HIV status, had endured sexual debut before the age of 17, and had abnormal vaginal bleeding in the formerly 12 months.

Only about 1 out of 4 women uses an modern contraceptive system insub- Saharan Africa(18). Reproductive age accounts for some differences in contraceptive system choice and provocations for use. Data collected between 2004 and 2010 in 18sub- Saharan African countries showed that the use of modern contraceptives to limit births was topmost among women 35 times of age and aged, while contraceptive use to space births was characteristic of women 25- 29 times of age(18). youthful women in our study may have been more interested in trying new technologies, especially short- term styles to space births. Cultural prospects for immature wedded women to have children sooner rather than subsequently(19) as well as beliefs regarding" having the right number of children"(20) could impact system choice, especially preferences that minimize discovery of use by others or lessen incapacity to conceive when use of a system has stopped.

Early induction of sexual intercourse(nuptial as well as extracurricular) among women has been shown to be associated with either low(21) or erratic(22) contraceptive use, including lower condom use to cover against HIV and other STIs. In our study, women with an age of sexual debut lower than 17 times may have been more interested in taking part in the study because they had presumably formerly endured at least one gravidity and were either using OCPs or DMPA. Since we did not enroll contraceptive- naïve women, it's unknown if their interest in an IVR would differ.

While women with one continuance sexual mate and those who did not have a recent mate of unknown HIV status were at lower trouble for HIV, their trouble for unintended gravidity and possibly unsafe recisions is unknown. The literature shows that women are more likely to hesitate condom use given enterprises about closeness and trust with a main mate(23). A recent qualitative study set up those condoms were not considered as contraception by immature Kenyan women(24). also, the perception that contraceptive use, including condom use, contribute to complaint, promiscuity, and infidelity has been suggested in several studies(24- 26).

Studies on the optimal rate of women enrolled to those screened for IVRs and other contraceptive technologies are stingy; thus, making it kindly

delicate to ascertain if our enrollment to webbing rate(ESR) was high or low. In Cameroon, a precautionary HIV/ STI trial of a vaginally fitted nonoxynol 9 showed a57.5 ESR(1317 enrolled among 2290 screened)(27). The US- predicated Contraceptive CHOICE Project, which examined choice of free reversible contraceptive, suggested a60.9 ESR(2500 enrolled out of 4107 screened)(28). While the ESR is kindly

advanced in these other studies, important contextual factors need to be taken into account for our sample(e.g., novelty of IVR, modern contraceptive use frequency, implicit incapacity to keep mate from knowing about IVR use). In addition, it's possible that our eligibility netting criteria may have affected our ESR by banning women who were HIV- infected or unfit to give documentation of DMAP or OCP use.

While highpre- use, information-only- predicated acceptance of an IVR is suggested, caution must be taken in interpreting our findings, especially given that amenability to switch to Nuva Ring was a study eligibility criterion. At ultimate, our findings may suggest that the vacuity of a new contraceptive option was appealing to women in our sample. This is further supported by results that showed that learning about modern family planning was the most common motivator for seeking study participation. In addition, enterprises with abnormal vaginal bleeding in the formerly 12 months that may have been associated with the contraceptive system reported at netting, especially DMPA(28), may have told women's amenability to try a new system. We admit that the NuvaRing information handed during the netting process, while thorough, does not give sufficient perceptivity on readiness and acceptance. The generality of acceptability consists of two factors(a) amenability, which gets at internal readiness or inclination to try a product in the future or to recommend its use to others, and(b) use, which transforms intentions into factual experience that generally involves following specified instructions for correct and harmonious use of a product or product cover(29). Womenpre- screened for our study reported high NuvaRing theoretical acceptability. An accurate assessment of contraceptive IVR acceptability will be dependent on completion of all phases of the study.

We observed high frequency of HIV, HSV- 2, and BV. The Government of Kenya has linked Kisumu as one of the top three counties with a hyperactive- endemic HIV burden, with frequency among women slightly advanced than that of all of Kenya(20.3 versus19.3, singly) and the median age of HIV accession significantly youthful among women than men(30). The literature shows that HSV- 2 and BV are significantly associated with a trouble for acquiring HIV(31), that HSV- 2 increases the trouble for BV(32), and that current and incident HSV- 2 infection is linked to an increased frequency of BV(33- 35). A comprehensive approach to women's sexual and reproductive health would be of benefit in this setting.

We set up a slightly advanced chance of women who reported sexual debut before the age of 15 than was reported in the 2011 Nyanza Province Multiple Indicator Cluster Survey(22.9vs.18.9), which may be attributed to our suvery administration mode(ACASIvs. face- to-face canvasser administered check) or the age of our actors(18- 34 timesvs. 15- 24 times)(36). The validation linking early sexual debut and continuance trouble for HIV infection for women in sub- Saharan Africa is colliding. A regular review showed a significant bivariate association between early sexual debut and HIV in advanced quality studies, while other studies set up either that subsequently serious sexual behavior

rather contributed to infection trouble, or that increased infection was explained by natural factors, including genital trauma at sexual debut performing from physically forced commerce(37).

A number of limitations are associated with this study. Due to convenience slice, women in our study may not be representative of women 18- 34 times of age living in Kisumu County; generalizability is an issue. We concentrated on women formerly using DMPA and OCPs; thus, it's unknown if women using other contraceptive styles or those without former contraceptive use experience may have characteristics that differ from our sample. Our findings can only give

perceptivity regarding women's theoretical acceptance of a contraceptive IVR; posterior analyses are demanded to examine factual use and adherence. While women neither entered eligibility criteria in advance ofpre- webbing nor were given specific reasons for ineligibility, there is the possibility that their inviting amenability to switch to the ring atpre- webbing was told by social desirability. In addition, some women may have recognized or learned from others that amenability to use the ring was an eligibility demand and that by furnishing a" yes" response this would help increase the liability that they would get into the study. Our recovery system, while harmonious with strategies for informing the community about happenings, may have prompted women to present for prescreening to avoid drawing attention to them by responding differently than their peers. It may have also minimized peer enterprises regarding a woman's gravidity or HIV status.

Conclusion

High Theoretical acceptance suggests feasibility for contraceptive IVR use. Factors associated with factual ring will use need to be assessed. To address the high HIV and STI frequency among immature women in this setting, theco- expression of hormonal contraception with antimicrobials may have enhanced uptake compared to rings for either suggestion alone.

Competing interests

The authors declare that they have no competing interests.

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