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Original research article

Effects of initiating a contraceptive implant on subsequent condom use: A randomized controlled trial☆,☆☆

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Abstract

Objective: To evaluate whether initiation of a contraceptive implant, a method of long-acting reversible contraception, reduces condom use, as measured by a biomarker of recent semen exposure [prostate-specific antigen (PSA)].
Study design: We conducted a randomized controlled clinical trial in which 414 Jamaican women at high risk for sexually transmitted infections (STIs) attending family planning clinics received the contraceptive implant at baseline ("immediate" insertion arm, *N*=208) or at the end ("delayed" insertion arm, *N*=206) of a 3-month study period. Participants were tested for PSA at baseline and two follow-up study visits and were asked about their sexual activity and condom use.
Results: At baseline, 24.9% of women tested positive for PSA. At both follow-up visits, the prevalence of PSA detection did not significantly differ between the immediate versus delayed insertion arm [1-month: 26.1% vs. 20.2%, prevalence ratio (PR)=1.3, 95% confidence interval (CI)=0.9–1.9; 3-month: 25.6% vs. 23.1%, PR= 1.1, 95% CI=0.8–1.6]. The change in PSA positivity over the three study visits was not significantly larger in the immediate arm compared to the delayed arm (1-sided p-value of .15).
Conclusions: Contraceptive implants can be successfully introduced into a population at high risk of unintended pregnancy and STIs without a biologically detectable difference in unprotected sex in the short term. This information strengthens the evidence to support promotion of implants in such populations and can help refine counseling for promoting and maintaining use of condoms among women who choose to use implants.
Implications: Sex unprotected by a condom was not higher over 3 months in women receiving a contraceptive implant, compared with those not receiving the implant.
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Keywords: Contraceptive implant; Randomized controlled trial; LARC; Condom use; PSA

1. Introduction

Unintended pregnancy continues to be an important public health issue worldwide. An estimated 213 million pregnancies occurred in 2012 worldwide and approximately 40% of those were unintended [1]. For Latin American and Caribbean populations, unplanned pregnancies represented 45% of all pregnancies in 2012 [1]. Unplanned pregnancies result from lack of contraceptive access, nonuse, incorrect or inconsistent use of contraceptives or contraceptive failure and have adverse health outcomes for women and infants, as well as financial,

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☆☆ Clinical Trial Registration: ClinicalTrials.gov, www.clinicaltrials.gov, (NCT01684358).

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and social consequences for women and their families, countries and societies [2–6].

Increasing use of long-acting reversible contraception (LARC) methods, such as subdermal contraceptive implants, by women of reproductive ages has been advocated as a strategy to reduce unintended pregnancy [7–12]. Of note, contraceptive implants have been shown to be highly effective, safe and cost effective and to require little user maintenance [8,10,13–15]. Implants, however, offer no protection against sexually transmitted infections (STIs), including HIV. Because of the high degree of effectiveness of implants against pregnancy, there is concern that women initiating such methods or their partners may be less motivated to use condoms, thus placing both partners at increased risk for HIV/STI [16,17]. Most available evidence suggests that LARC is associated with a greater reduction in condom use than other less effective methods such as oral contraceptives and injectables [18–22], although this finding has not been consistently demonstrated [23,24]. However, all of these studies have been limited by a lack of randomized design, small sample sizes or reliance on self-reports of condom use with unknown validity. Given these limitations, we conducted a randomized clinical trial with a delayed intervention control group to assess whether initiation of a contraceptive implant would lead to less condom use as measured with prostate-specific antigen (PSA), a vaginal biomarker of recent semen exposure [25–28].

2. Material and methods

2.1. Study population

Study participants were referred and recruited from seven maternal and child health and family planning public clinics in Kingston, Jamaica, and through peer-to-peer referrals. Recruitment took place from September 2012 to October 2013 with follow-up visits continuing until January 2014. Women were eligible for enrollment if they were willing to be randomized to receive Sino-implant (II) immediately or after a 3-month delay, were 18–44 years of age, were not currently using or planning to use another LARC method in the next 3 months, had not had a hysterectomy or planned to have one in the next 3 months, were deemed to be a good candidate for enrollment by the study clinicians and had no contraindications to hormonal implant use per the World Health Organization's guidance [13]. Contraindications consisted of lactating and within first 3 weeks postpartum, acute deep venous thrombosis or pulmonary embolism, systemic lupus erythematosus, migraine with aura, unexplained vaginal bleeding and current or past history of ischemic heart disease. Finally, women known to be HIV infected based on self-report or a previous positive test were excluded from this study, because this population could have differed with respect to motivations to use condoms and they tended to receive more intensive safer-sex counseling than other women.

Women who provided written informed consent for enrollment received a urine test to screen for pregnancy. Women who had a positive urine pregnancy test were discontinued from the study and were referred to prenatal services.

2.2. Study product

Sino-implant (II) is a two-rod contraceptive implant containing 75 mg levonorgestrel in each rod. It is manufactured in China, by the Shanghai Dahua Pharmaceutical Company, and marketed in more than 20 countries under the names of Zarin, Trust, Simplant or Femplant [29]. Once inserted, the implant is effective for up to 4 years. Prior to study initiation, the Jamaican Ministry of Health approved (on April 27, 2012) the registration of the Sino-implant (II) for distribution and use in the country.

2.3. Study design

Using permuted block randomization performed by a pseudorandom number generator and a system of sequentially numbered, sealed envelopes, women were randomly assigned to one of two study arms: (1) "immediate" insertion at baseline or (2) "delayed" insertion after 3 months of follow-up. Participants and local staff were not blinded to intervention arm assignment; however, laboratory staff remained blinded throughout the study.

At baseline, study nurses orally administered questionnaires to collect information on participant demographics, sexual activity and condom use. Study clinicians provided safer-sex and contraceptive counseling, conducted clinical assessments and physical (including pelvic) examinations and collected vaginal swabs. After 39 weeks of enrollment and follow-up, the Pregnancy Exclusion Checklist [30] was incorporated into the contraceptive counseling session as an additional way to screen out very early pregnancies undetectable with a urine pregnancy test. The randomization envelope was opened after safer-sex counseling was provided in order to ensure that participants in both study arms received the same condom counseling messages. Vaginal swabs were tested for PSA, which is a biomarker of semen detectable for up to 48 h postexposure [25–28,31]. Study clinicians inserted the Sino-implant (II) into participants who were randomized to the immediate insertion arm and provided male condoms. In addition, women randomized to the delayed insertion arm were provided male condoms and, if desired, oral contraceptives for the 3-month follow-up period.

Women were scheduled to return to the clinic for follow-up at 1 and 3 months after enrollment. At both follow-up visits, study staff again administered a questionnaire, conducted safer-sex and contraceptive counseling, conducted clinical assessments and physical (including pelvic) examinations, collected vaginal swabs and distributed male condoms. Women in the immediate insertion arm were administered a questionnaire to assess implant