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Effect of injectable contraceptive use on response to antiretroviral therapy among women in Rakai, Uganda

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Abstract

Background—There is limited evidence on the effect of injectable contraception on response to antiretroviral therapy (ART).

Design—Using modified Poisson regression, we assessed data from 418 female Ugandan ART initiators to examine the effect of injectable contraceptive use on a composite virologic failure outcome (defined as failure to achieve virologic suppression, switch to second line therapy, or death within 12 months of ART initiation), and also assessed ART adherence.

Results—About 12% of women reported using injectable contraceptives at ART initiation, and their composite virologic failure rates 12 months later were similar to women not using injectable contraceptives at ART initiation (11% vs. 12%, p=0.99). Multivariable Poisson regression suggested no significant differences in virologic failure by injectable contraceptive use at baseline (PRR: 0.85, p=0.71), but power was limited. Adherence to ART increased with time since ART initiation, but did not appear to differ between injectable contraceptive users and non-users.

Conclusions—Consistent with current WHO guidelines, our results suggest no deleterious effect of injectable contraceptive use on response to ART, but power was limited, injectable contraceptive use patterns over time were inconsistent, and additional evidence is needed.

Keywords

family planning; hormonal contraception; injectable contraception; HIV; antiretroviral therapy; Uganda

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1. Introduction

Use of an effective contraceptive method reduces unintended pregnancy and the demand for abortion, and decreases maternal morbidity and mortality [1]. When used by HIV-infected (HIV+) women who wish to avoid pregnancy, contraception can also reduce mother-to-child HIV transmission [2]. Hormonal contraceptive methods are among the most effective methods of pregnancy prevention. In theory, certain methods of hormonal contraception (HC) could interact with antiretroviral therapy (ART) to decrease ART efficacy, decrease HC efficacy, or increase side effects [3]. Decreased ART drug levels could lead to drug resistance, treatment failure, and potentially increased mortality. Certain ART drugs, such as nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), are not expected to interact with HC [4, 5], but protease inhibitors (PIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) share common hepatic metabolic pathways with certain HC methods.

Based on current evidence, the World Health Organization guidelines suggest that HIV+ women, including those on antiretroviral therapy (ART), can generally use HC with two exceptions: (1) women on ritonavir-boosted PIs are not recommended to use combined hormonal methods containing both an estrogen and a progestin, or progestin-only pills, due to concerns about potential decreased contraceptive effectiveness, and (2) women with AIDS who are clinically ill while on ART are not recommended to receive insertion of an intrauterine device (whether hormonal or non-hormonal), due to concerns about pelvic inflammatory disease [6, 7]. Consistent condom use is recommended to prevent HIV transmission to sexual partners and provide backup protection against pregnancy.

Injectable contraceptive methods are among the most popular HC methods in Eastern and Southern Africa, and their popularity is increasing rapidly [8]. In Rakai, Uganda, the primary injectable contraceptive method is a progestin-only formulation, depot medroxyprogesterone acetate (DMPA). Studies assessing pharmacokinetic interactions between injectable contraceptives and various ART regimens generally suggest that injectable contraceptives can be safely used by HIV+ women [9–11], although one study observed clinically insignificant changes in drug exposure to nelfinavir and nevirapine when taken with DMPA [12]. These studies followed women for 12 weeks and included a maximum of 70 participants. One study followed participants over three years, and using propensity score matching to control for differences between 77 HC users and 77 non-users, found no differences in CD4 count or log viral load response after ART initiation, but did not differentiate between oral contraceptive pills, injectable contraceptives, or levonorgestrel implants [13]. To our knowledge, no previous study has specifically assessed the effect of injectable contraceptives on response to ART over a period greater than 3 months.

Our objectives were to assess the effect of injectable contraceptive use on a composite outcome of failure to achieve virologic suppression at one year, regimen change, or death among sexually active HIV+ women on ART in Rakai, Uganda, and to examine whether use of injectable contraceptives was associated with poorer adherence to ART, since regimen complexity may contribute to non-adherence (and thus lower efficacy) of either regimen [14].

2. Materials and methods

The Rakai HIV Care Program is a community HIV care service provided to the Rakai District of Uganda, with regularly scheduled visits for patient monitoring and free drug resupply. Clients are typically seen weekly for the first month, every two weeks until month 3, and monthly until 12 months. Depending on adherence status, patients are then followed every 2 or 3 months. A variety of family planning services are available to clients, including condoms and HC methods. ART is provided for individuals with CD4 cell count ≤250 cells/

mm^3 and/or WHO clinical stage IV disease, and standard first-line regimens include zidovudine or stavudine, lamivudine, and nevirapine or efavirenz. A record of drug regimens, adherence to ART, CD4 and VL measurements (performed every 6 months), contraceptive use, and pregnancies are maintained in electronic clinic records.

We included sexually active women who initiated ART within the Rakai Health Sciences Program (RHSP) HIV care program after January 10, 2006 (when we began collecting information on HC use in ART clinic records), who had information at baseline on viral load (VL), and who had provided consent for use of their medical records for research purposes. We excluded women diagnosed with tuberculosis within the first year of ART, since tuberculosis treatment may impact response to ART [15]. We did not exclude women who were pregnant at baseline, since pregnancy is associated with the absence of effective contraception, could theoretically impact response to ART [16], and thus could be on the causal pathway in the relationship between injectable contraception and virologic failure. HIV-1 VL testing was performed using the Roche Amplicor 1.5 Monitor assay (Roche Diagnostics, Indiana, USA) with a lower limit of detection of 400 copies/mL.

We assessed the effect of injectable contraceptive use as reported at ART initiation on a composite failure outcome which included (a) failure to achieve virologic suppression at 12 months after ART initiation, defined as VL ≥400 copies/mL, (b) switch from first-line to second-line therapy within 12 months of ART initiation (unless due to drug toxicity), or (c) death within 12 months of ART initiation. A small proportion of women (8%, 35/433) were missing a 12-month VL measurement. For seven of these women, we imputed information using VL measurements taken 6 and 18 months after ART initiation. We assumed an undetectable VL at 12 months in five women with undetectable VL at 6 and 18 months, detectable VL at 12 months in one woman with detectable VL at 6 and 18 months, and detectable VL at 12 months in one woman with undetectable VL at 6 months and a high VL (910,626 copies/mL) at 18 months. The remaining 28 women were considered lost to follow-up, and a sub-analysis included loss to follow-up as part of the composite failure outcome, since obtaining alternate services locally is unlikely.

Since some women died or were lost to follow-up prior to 12 months after ART initiation, our original analysis could not control for adherence to ART throughout the first year of treatment. Since ART adherence is strongly related to treatment outcomes and often improves with time, a second analysis was restricted to women who remained alive and on ART for at least one year after ART initiation. In this analysis, exposure was defined as ever vs. never use of injectable contraceptives at any point during the first year of ART treatment. Our composite outcome included failure to achieve virologic suppression or switch to a second-line ART regimen. Adherence to ART was calculated as the average percentage of days each patient reported taking ARVs as prescribed, a measure which has been shown to reflect true adherence [17, 18]. We compared ART adherence as reported at 6 and 12 months by injectable contraceptive use or non-use.

2.1 Statistical analysis

We calculated descriptive statistics for baseline characteristics by injectable contraceptive use, using the nonparametric Mann-Whitney U test to evaluate differences in medians, and Pearson's chi-square or Fischer's exact test for categorical variables. Since the outcome could be considered common (>10%), we estimated the association between injectable contraceptive use and the composite outcome using a "modified" Poisson regression model with a robust error variance to obtain prevalence risk ratios (PRR) [19]. We tested for differences in adherence by injectable contraceptive use using Pearson's chi-square test. All analyses were done using Stata/SE 10.1. Ethical approval was obtained from the Science and

Ethics Committee of the Uganda Virus Research Institute and the Ugandan National Council for Science and Technology.

3. Results

Data were available for 418 female ART initiators (Table 1), including 367 women not using any HC method at baseline and 51 women using injectable contraceptives at baseline (15 women using oral contraceptive pills at baseline were excluded from the analysis). A small proportion of women (10%, n=41) were age 18–24 years, over half (55%, n=231) were age 25–34 years, and about a third (35%, n=146) were over 35 years old. A very small proportion (6%, n=23) had never been married, but only 56% (n=232) were currently married or cohabitating. The majority (87%, n=364) reported zero or one recent sexual partner, but about 8% (n=32) reported two or more partners (5%, n=22, had missing information). About 8% (n=33) of women were pregnant at ART initiation. At baseline, 49% (n=204) reported never using condoms, 12% (n=52) reported sometimes using condoms, and 39% (n=162) reported always using condoms. Women had a median CD4 cell count of 191 cells/mm^3 within 0–3 months prior to ART initiation.

About 12% (n=51) of women reported use of injectable contraceptives at baseline. These women were significantly less likely than women not using injectable contraception at baseline to be pregnant (0% vs. 9%, p=0.02) or to report consistent condom use (22% vs. 41%, p=0.02). We found no statistically significant differences by injectable contraceptive use in age, marital status, number of recent sexual partners, or CD4 count near ART initiation. Although the overall proportion of women reporting injectable contraceptive use was 12% at all time points, use in individual women was inconsistent over time. Among 61 women who ever used injectable contraceptives and did not report use of any other HC method at any of the three visits (baseline, 6 months, or 12 months), 31% initiated injectable contraceptive use at 6 or 12 months, 36% discontinued injectable contraceptive use at 6 or 12 months, 18% fluctuated in injectable contraceptive use over the three visits, and only 15% reported injectable contraceptive use at all three visits. Among these 61 women, 43% reported injectable contraceptive use during at least two consecutive visits (baseline and 6 months, or 6 months and 12 months, or all three visits).

Among 390 individuals with complete outcome information, 48 (12%) met the criteria for the composite outcome for treatment failure at 12 months (Table 2). Failure was significantly associated with having a lower CD4 count prior to ART initiation (p=0.05), and marginally associated with younger age (p=0.07) and being previously married (p=0.10). Defining 28 women lost to follow-up as failures increased the proportion meeting the criteria for failure to 76/418 women (18%). Women using injectable contraceptives at baseline were marginally (p=0.13) more likely to be lost to follow-up.

Use of injectable contraceptives at baseline was not associated with the composite outcome for treatment failure at 12 months (prevalence risk ratio (PRR): 0.89, p=0.80), but power was limited and use of injectable contraceptives over time was inconsistent. When loss to follow-up was included as part of the composite treatment failure outcome at 12 months (PRR: 1.22, p=0.50), the direction of the estimate changed, but did not reach statistical significance (Table 3). When we controlled for age, consistency of condom use, and number of recent sexual partners, PRRs remained similar (PRR: 0.85, p=0.71, and PRR: 1.18, p=0.55 including losses to follow-up as failures).

A sensitivity analysis restricted to 263 women with complete follow-up and adherence information who never used pills or Norplant assessed the relationship between ever use of injectable contraceptives at any time point and failure to achieve virologic suppression at 12 months or drug regimen change. Ever use of injectable contraceptives was not significantly

associated with failure (defined as detectable viral load or regimen switch at 12 months after ART initiation) in univariable (PRR: 0.95, p=0.90) or multivariable regression including adjustment for adherence (PRR: 0.82, p=0.65), but power was limited and injectable contraceptive use over time was inconsistent. Having multiple sexual partners was significantly associated with virologic failure (PRR: 2.52, p=0.03) and ART adherence <95% at 6–12 months was marginally associated with failure (PRR: 1.98, p=0.12) (data not shown).

Among these 263 women, ART adherence appeared to improve over time. Only 29% (n=75) of these women reported 100% adherence 0–6 months after ART initiation, while 75% (n=198) reported 100% adherence during the second half of the year. Using chi-square tests, we assessed whether adherence at 6 and 12 months was associated with injectable contraceptive use as reported 6 months prior, or as reported concurrently. We found no statistically significant differences in ART adherence for users and non-users of injectable contraceptives. At six months, 29% (n=10) of the 35 women using injectable contraceptives at baseline and 29% (n=65) of the 228 women not using injectable contraceptives at baseline reported 100% ART adherence (p=0.99), while 36% (n=12) of the 33 women currently using injectable contraceptives and 27% (n=63) of the 230 women not currently using injectable contraceptives reported 100% ART adherence (p=0.29). At 12 months, 76% (n=25) of the 33 women using injectable contraceptives at 6 months and 75% (n=173) of the 230 women not using injectable contraceptives at 6 months reported 100% ART adherence (p=0.95), while 78% (n=25) of the 32 women currently using injectable contraceptives and 75% (n=173) of the 231 women not currently using injectable contraceptives reported 100% ART adherence (p=0.69).

4. Discussion

We did not find that injectable contraceptive use was associated with increased risk of ART failure as measured by detectable VL, regimen change, or death at 12 months after ART initiation, nor did we find evidence that injectable contraceptive use was associated with poorer adherence to ART. Although power was limited and use of injectable contraceptive over time was inconsistent, our results are consistent with current WHO recommendations for injectable contraceptive use among HIV+ women on ART, and support the findings of previous studies [9, 10, 12].

We assessed virologic (as opposed to immunologic) failure as part of our composite outcome, since immunologic criteria for identifying ART failure perform poorly in this population and since immunologic failure has been shown to lag behind virologic failure [20, 21]. However, the optimal VL threshold for defining virologic failure has not been determined [22]. We assessed VL at 12 months after ART initiation for two main reasons. First, adherence to ART was poor at the start of ART, so using earlier (6 month) VL measurement could have limited our ability to detect any effects of potential drug interactions between ART and injectable contraception. ART adherence improved dramatically between months 0–6 (29% reporting perfect adherence) and months 6–12 (75% reporting perfect adherence). Second, given variation in individual contraceptive use over time, using a VL measurement taken much later (i.e., 18 months and beyond) could have increased the potential for exposure misclassification in our primary analysis on injectable contraceptive use at ART initiation. Among all women who reported any use of injectable contraceptives, 43% reported use during at least two consecutive visits, suggesting at least 6 months of continuous contraceptive effect. Notwithstanding that the lack of sustained injectable contraceptive use complicates interpretation of our results, our findings add to the limited body of evidence on injectable contraceptive use and ART. Injectable contraceptives are the most popular HC method in Rakai and among all women initiating ART in our

sample, 12% reported use of injectable contraceptives at baseline, which is comparable with the 16% of all HIV+ women (regardless of ART use) who reported use of injectable contraceptives in Rakai between 2004 and 2006 [23].

Our analysis has limitations. Due to low ART failure rates and limited numbers of injectable contraceptive users, power to detect effects was limited. However, to our knowledge, no previous studies have specifically assessed the effect of injectable contraception to ART over a period of greater than 3 months or with more than 70 participants, so this analysis contributes to scarce literature in which more evidence is needed. In addition, data were drawn from a clinical database, and we were unable to control for factors such as alcohol use, education, socioeconomic status, and parity, which may be related to use of injectable contraceptives, ART adherence, and virologic suppression [24]. Contraceptive use was self-reported and thus subject to error, and inconsistent injectable contraceptive use might result in exposure misclassification. However, analyses incorporating information on injectable contraceptive use at follow-up visits suggested similar results to our main analysis.

Women in sub-Saharan Africa may be more likely to enroll into HIV care [25] and to initiate ART than men [26]. As access to ART increases, an increasingly larger number of reproductive-age women will require counseling on simultaneous use of HC and ART. Despite the personal and public health impacts of unintended pregnancies to HIV+ women, providers in some settings are reluctant to give HC to women on ART [3]. Limited evidence suggests that pregnancy itself may have adverse effects on virologic response to ART [16], though evidence is conflicting [27] and limited. Additional studies assessing the relationship between hormonal contraceptive methods, including injectable contraception, and response to ART are needed, particularly those that incorporate longer follow up times, consistent exposure to HC use, and greater statistical power.

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Table 1

Injectable contraceptive use by demographic, sexual, and health characteristics at ART initiation

	Total n=418	No HC use at baseline n=367 (88%)	Injectable contraceptive use at baseline N=51 (12%)	p- value for χ^2
	n (%)	n (%)	n (%)	
Failure (detectable VL at 12 months, regimen change, or death)[†]	48 (11)	43 (12)	5 (11)	0.99
Age (years)				0.22
18–24	41 (10)	38 (10)	3 (6)	
25–34	231 (55)	197 (54)	34 (67)	
35–60	146 (35)	132 (36)	14 (27)	
Marital status				0.75
Never married	23 (6)	20 (6)	3 (6)	
Married/cohabitating	232 (56)	206 (56)	26 (51)	
Previously married	163 (39)	141 (38)	22 (43)	
Pregnant at baseline	33 (8)	33 (9)	0 (0)	0.02
Condom use				0.02
Never	204 (49)	173 (47)	31 (61)	
Sometimes	52 (12)	43 (12)	9 (18)	
Always	162 (39)	151 (41)	11 (22)	
Sex partners past 6 months				0.30
None or one	364 (87)	322 (88)	42 (82)	
2–10	32 (8)	28 (8)	4 (8)	
Missing information	22 (5)	17 (5)	5 (10)	
CD4 0–3 months prior to ART initiation, n (median)[‡]	380 (191)	331 (191)	49 (189)	0.62

[†] Excludes 28 individuals presumably alive at 12 months, but without a 12 (or 6 and 18) month VL measurement.

[‡] 38 individuals excluded as final CD4 measurement prior to ART initiation was not within 0–3 months of ART initiation, p-value for Mann-Whitney U test.

Table 2

Association between ART failure (detectable viral load, drug regimen change, or death) over 12 months and demographic, sexual, and health characteristics at ART initiation

	Total n=390*	No failure n=342 (88%)	Failure n=48 (12%)	p-value for χ^2
	n	n (%)	n (%)	
Injectable contraceptive use at baseline				0.99
Not using injectable contraception	345	302 (88)	43 (12)	
Using injectable contraception	45	40 (89)	5 (11)	
Age (years)				0.07
18–24	40	35 (88)	5 (13)	
25–34	213	180 (85)	33 (15)	
35–60	137	127 (93)	10 (7)	
Marital status				0.10
Never married	21	19 (90)	2 (10)	
Married/cohabitating	221	200 (91)	21 (10)	
Previously married	148	123 (83)	25 (17)	
Pregnant at baseline	30	27 (90)	3 (10)	0.99
Condom use				0.17
Never	192	170 (89)	22 (11)	
Sometimes	48	38 (79)	10 (21)	
Always	150	134 (89)	16 (11)	
Sex partners past 6 months				0.13
None or one	337	297 (88)	40 (12)	
2–10	31	24 (77)	7 (23)	
Missing information	22	21 (95)	1 (5)	
CD4 0–3 months prior to ART initiation, n (median)≠	380 (191)	308 (196)	44 (151)	0.05

≠10 individuals excluded as final CD4 measurement prior to ART initiation was not within 0–3 months of ART initiation, p-value for Mann-Whitney U test.

*Excludes 28 women without a 12 (or 6 or 18) month viral load measurement.

Table 3

Univariable and multivariable associations between injectable contraceptive use vs. no HC use at baseline and ART failure

	Univariable PRR			Multivariable PRR		
	PRR	**95% CI**	**p**	**PRR**	**95% CI**	**p**
Baseline injectable contraceptive use						
Detectable VL at 12 mos, regimen switch, or death[†] (among 390 women)	0.89	0.37–2.14	0.80	0.85	0.37–1.99	0.71
Detectable VL at 12 mos, regimen switch, death, or loss to follow-up[†] (among 418 women)	1.22	0.69–2.15	0.50	1.18	0.68–2.04	0.55
Ever injectable contraceptive use						
Detectable VL at 12 mos, regimen switch (restricted to 263 one-year survivors)[‡]	0.95	0.40–2.24	0.90	0.82	0.35–1.93	0.65

[†]Multivariable analysis controlled for age at ART initiation, consistency of self-reported condom use during past six months, and number of sexual partners during past six months.

[‡]Multivariable analysis controlled for age at ART initiation, consistency of self-reported condom use during last 1.5 years, number of recent sexual partners during last 1.5 years, and self-reported ART adherence from 6 to 12 months after ART initiation.