



Original article

Depot Medroxyprogesterone Acetate Use Is Not Associated With Risk of Incident Sexually Transmitted Infections Among Adolescent Women

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A B S T R A C T

Purpose: To determine whether depot medroxyprogesterone acetate (DMPA) use is associated with an increased risk of acquisition of sexually transmitted infections (STIs) in a cohort of healthy adolescents, for whom prospective evidence is sparse.

Methods: Adolescent women aged 14–17 years ($n = 342$) were recruited from clinical sites in the United States between 1999 and 2005. They returned quarterly for interviews and STI testing. During alternating 3-month periods, participants also completed daily diaries of sexual behaviors and performed weekly vaginal self-obtained swabs to test for STIs. Data collected through 2009 (median follow-up length = 42.2 months) were analyzed. Univariable and multivariable tests of association between STI acquisition during the 3-month diary period and covariates were calculated, using nonlinear mixed-effect logistic regression models to control for repeated measurements.

Results: In multivariable analysis, there were no significant associations between DMPA use in the current or previous 3-month period and incidence of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, or *Trichomonas vaginalis*. The number of total or unprotected sexual events during the diary period was not associated with the risk of STI. Older age was a protective factor for the development of *Chlamydia trachomatis* (odds ratio = .85; 95% confidence interval = .76–.96). The only factor significantly associated with an increased risk of contracting all three STIs was a greater number of sexual partners during the diary period (odds ratio, range = 1.91–2.62).

Conclusions: In this U.S.-based cohort of adolescent women, we found no evidence that DMPA use was associated with increased STI risk. Efforts to curb STI transmission among adolescents should focus on education about the reduced number of sexual partners.

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IMPLICATIONS AND
CONTRIBUTION

This study adds to the sparse prospective literature on DMPA use and the acquisition of STIs in adolescents. DMPA should not be avoided in adolescents because of concern for increased STI risk. Rather, prevention efforts should focus on education regarding a reduced number of sexual partners.

National data indicate that nearly 40% of sexually experienced adolescents (aged 14–19 years) in the United States are infected with at least one sexually transmitted infection (STI) [1]. Clearly,

behavioral factors such as unprotected intercourse and multiple partners are associated with increased risk of STIs. More recently, studies have investigated the relationship between STI acquisition and biological risk factors, including cervical ectopy, age, coinfection with other STIs, and use of hormonal contraception, such as oral contraceptive pills and depot medroxyprogesterone acetate (DMPA) [2–6]. These latter studies have suggested that hormonal contraception may increase the risk of STI acquisition. One widely postulated mechanism is the promotion of cervical

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ectopy by exogenous hormones. Both human and animal models have demonstrated an association between hormonal contraceptive use and increased cervical ectopy [7,8]; however, findings from studies assessing the association between cervical ectopy and infection risk have been inconsistent [9–12]. Additionally, the literature on hormonal contraceptive use and STI risk has demonstrated methodological shortcomings including cross-sectional study design and lack of controlling for important confounders such as sexual behavior. Thus, we lack clear evidence that hormonal contraceptive use is an independent risk factor for acquisition of STIs.

Investigation of the relationship between DMPA use and STI acquisition is particularly important for adolescents because of the popularity of DMPA in this demographic: it is highly effective, requires no daily behaviors, and is not partner dependent [13]. National data indicate that rates of current DMPA use are highest among adolescent women aged 15–19 years (at 9.4%) [14] and 20% of sexually experienced adolescents have ever used DMPA [15].

Prospective cohort studies examining the association between DMPA and acquisition of *Chlamydia trachomatis* (*C trachomatis*), *Neisseria gonorrhoeae* (*N gonorrhoeae*), and *Trichomonas vaginalis* (*T vaginalis*) are few and are limited by small sample sizes and lack of adjustment for confounding. Of the five studies in existence, three [16–18] have found statistically significant associations between DMPA use and *C trachomatis* infection with hazard ratios ranging from 1.6 to 4.3. None have observed increased risk of *N gonorrhoeae* [16,17,19,20] or *T vaginalis* [16,19,20] infection. All five studies used interviews to retrospectively gather data about sexual behaviors during the previous week or months, which likely resulted in significant recall bias. In addition, two of the studies [16,17] were completed in populations of sex workers and two in HIV-positive women [17,19], which limits their generalizability.

Our study seeks to fill gaps in the literature by investigating whether DMPA is associated with an increased risk of acquisition of *C trachomatis*, *N gonorrhoeae*, and *T vaginalis*, independent of other behavioral risk factors. We studied a cohort of healthy adolescents, using sensitive methodologies for STI testing and daily diary reports of sexual behaviors, to adequately control for behavioral confounders. In this prospective cohort study, we hypothesize that DMPA is not an independent risk factor for acquisition of *C trachomatis*, *N gonorrhoeae*, or *T vaginalis*.

Methods

Study design

The data used for this analysis were collected as part of the Young Women's Project (YWP). The YWP is a longitudinal study of a convenience sample of adolescent women. The study design has been detailed in previous publications [21]. Briefly, adolescent women were recruited from clinical sites and followed up longitudinally. Enrollment began in 1999 and ended in July of 2005; the last observations (interviews) were conducted in March of 2009. The study was originally designed for 27 months of observation, but was extended up to 75 months for some participants who were re-enrolled for a second period of variable observation. At follow-up visits, which occurred approximately every 3 months, participants were interviewed about their sexual behaviors over the previous 3 months. STI testing was conducted at each 3-month visit. During every other 3-month period, participants completed daily diaries of sexual behaviors and

performed weekly vaginal self-obtained swabs to test for STIs. The research was approved by the institutional review board of Indiana University-Purdue University at Indianapolis, IN.

Population

Young women were recruited from three adolescent medicine clinics in inner-city Indianapolis, IN. Eligible women were aged between 14 and 17 years, were English-speaking, and were without significant psychiatric or substance abuse disorders. Eligible participants who wished to participate were enrolled in the clinic. At enrollment, informed consent was obtained from participants, and parental permission was also obtained.

Data collection

On enrollment, participants completed a written questionnaire and a face-to-face interview to ascertain sexual behaviors and STI history. Participants were asked to report their lifetime and recent (past 3 months) experience with vaginal, oral, and anal sex; their number of sexual partners; frequency of sexual intercourse; past contraceptive use; history of STIs; and age at first intercourse. Clinician-obtained cervical samples or participant-obtained vaginal samples were also collected for STI testing.

Study participants returned to the clinic for follow-up every 3 months for interviews and STI testing. The interviews focused on sexual and other health behaviors and contraception use during the previous 3 months. Clinician-obtained cervical samples or participant-obtained vaginal samples were collected for STI testing. Self-administered vaginal swabs have shown high acceptability, sensitivity, and specificity [22].

In alternating 3-month blocks, study participants completed daily diaries describing sexual behaviors, and they collected weekly vaginal swabs for STI testing. Vaginal swabs were retrieved weekly by study personnel, were batched, and were processed at the end of each 3-month period. All diary periods lasted approximately 84 days and were initiated and ended by a clinic visit as described.

DMPA use was assessed at the quarterly interviews; these quarterly interviews flanked the diary periods and were used to assess the use of DMPA in the 3 months before a diary phase and then to assess actual DMPA use during the diary period. Participants were asked, "Have you used Depo-Provera over the last 3 months?" If they answered "yes," participants were asked to report date of last injection. During the first 27 months of interviews, DMPA injections were verified through medical records. Self-reports of DMPA use were found to be highly accurate, and medical records verification was dropped. In most cases, DMPA was administered at the same time of the quarterly interview, as interviews were scheduled to coincide with clinical appointments for participants' convenience. For this analysis, a diary period was labeled with DMPA if the participant reported yes to having used DMPA over the last 3 months.

STI testing

C trachomatis, *N gonorrhoeae*, and *T vaginalis* infections were identified from the in-clinic visits, the participant-obtained vaginal samples collected weekly during diary collection, and the episodes of infection identified from the participants' medical records. Testing was performed within 24–48 hours after specimen collection during the quarterly interview. Participant-

obtained samples were batched and tested at the end of the 3 month diary collection period. Nucleic acid amplification tests (NAATs) were used to analyze all study specimens for *C trachomatis* and *N gonorrhoeae* (Amplicor CT/NG PCR; Roche Diagnostics, Indianapolis, IN). Because of false-positive NAAT results for *N gonorrhoeae*, samples testing positive by the Amplicor CT/NG PCR were confirmed by Gen-Probe (San Diego, CA) Aptima, which amplifies a different molecular target [21]. Detection of *T vaginalis* DNA was performed using a modification of the Amplicor CT/NG PCR assay that included primers and probes specific for *T vaginalis*. Positive STI test results from medical records (not including times of study participation) were obtained from the Regenstrief Medical Record System (Regenstrief Institute, Inc, Indianapolis, IN), an electronic medical record system that links most hospitals, primary care, and acute care facilities in Indianapolis, IN.

STI treatment

Results of STI testing at enrollment, follow-up visits, and self-administered vaginal swabs were available to research and clinic staff within 72 hours of sample collection. Participants received treatment according to published guidelines, typically within 1 week of the positive test. Research staff was diligent in providing prompt treatment, but test of cures were assessed at the following quarterly visit. Antibiotic types and regimens were recorded for each treatment. Study participants who developed STI symptoms between follow-up visits were tested and treated at the study center. Documentation of treatment of infections was also gathered from medical records.

Data analysis

Demographic, behavioral, and clinical characteristics of study participants were summarized and reported using descriptive statistics as appropriate. The unit of analysis was the actual diary period, and the event of interest was STI acquisition during the 3 month diary period. Diary periods provided information on potential confounders, including daily reports of vaginal intercourse and condom use on the day of vaginal intercourse, whereas number of lifetime partners and partners numbers over the previous 3 month period were collected from quarterly interviews. Diary periods with concurrent use of DMPA and another form of hormonal contraception (i.e., oral contraceptive pills or the contraceptive patch) were excluded from analysis. Additionally, diary periods were excluded if the participant had a positive test for *C trachomatis*, *N gonorrhoeae*, or *T vaginalis* at the start of the period without documentation of adequate treatment, or if either the initial or the final STI test was missing. This level of exclusion was specific to each STI analyzed. Univariable and multivariable tests for association between STI acquisition and covariates were calculated using non-linear mixed-effect logistic regression models (to control for repeated measurements), and odds ratios with 95% confidence intervals were presented. Covariates included in the models were clinically significant variables that have been previously identified to be associated with sexually transmitted infection [20,23,24]: DMPA use during the current diary period, and DMPA use during the previous 3 month period (representing longer exposure); age; presence of positive STI test at the start of a diary period; number of lifetime sexual partners; and number of sexual partners in the

Table 1
Disposition of study participants and diary periods

Characteristic	Number of participants	Number of diary periods		
		<i>C trachomatis</i>	<i>N gonorrhoeae</i>	<i>T vaginalis</i>
Enrolled	387			
Excluded	45			
No follow-up visit	22			
Missing first interview with DMPA data	2			
Missing STI data	9			
OCP use only	12			
Total in analysis	342			
Accessible for analysis		2,535	2,535	2,535
Excluded		684	675	671
Concurrent OCP use		551	551	551
No STI treatment data		37	28	36
No STI testing (day 1)		86	86	80
No STI testing (final day)		10	10	4
Total in analysis		1,851	1,860	1,864
Using DMPA at enrollment	118			
Number of diary periods contributed (%)				
1	4 (3.4)			
2	12 (10.2)			
3	8 (6.8)			
4 or more	94 (79.7)			
Mean (SD)	6.3 (3.0)			
Not using DMPA at enrollment	224			
Number of diary periods contributed (%)				
1	26 (11.6)			
2	29 (12.9)			
3	24 (10.1)			
4 or more	145 (64.7)			
Mean (SD)	5.1 (3.0)			

C trachomatis = *Chlamydia trachomatis*; *N gonorrhoeae* = *Neisseria gonorrhoeae*; *T vaginalis* = *Trichomonas vaginalis*; DMPA = depot medroxyprogesterone acetate; OCP = oral contraceptive pill; STI = sexually transmitted infection; SD, standard deviation.

Table 2
Participant characteristics at enrollment by DMPA use at enrollment

Characteristic	DMPA n (%)	No hormonal n (%)	All n (%)
Total number	118 (34.50%)	224 (65.50%)	342
Age (years) at enrollment: mean $\pm$ SD	15.65 $\pm$ 1.10	16.01 $\pm$ 1.09	15.77 $\pm$ 1.11
Age (years) at first sex: mean $\pm$ SD	13.72 $\pm$ 1.59	14.34 $\pm$ 1.96	14.13 $\pm$ 1.86
African American	107 (90.68%)	200 (89.29%)	307 (89.77%)
Positive STI	24 (20.34%)	33 (14.73%)	57 (16.67%)
Positive CT	20 (16.95%)	20 (8.97%)	40 (11.73%)
Positive GC	6 (5.08%)	8 (3.59%)	14 (4.11%)
Positive TV	2 (1.69%)	15 (6.70%)	17 (4.97%)
Number of partners in past 2 months: mean $\pm$ SD	1 $\pm$ 1	1 $\pm$ 1	1 $\pm$ 1
Number of lifetime partners: mean $\pm$ SD	3 $\pm$ 3	3 $\pm$ 4	3 $\pm$ 4

CT = *Chlamydia trachomatis*; GC = *Neisseria gonorrhoeae*; TV = *Trichomonas vaginalis*.

past 3 months, number of sexual events, and number of unprotected sexual events during the diary period. All covariates were included in both univariable and multivariable models. Data analysis was performed using SAS for Windows version 9.1 (SAS Institute, Cary, NC).

Results

Study population characteristics

Three hundred eighty-seven adolescents were enrolled and followed up in the YWP, contributing 2,535 diary periods. At 27 months, 285 (73.8%) of the 387 women had completed the entire observation period and 246 were re-enrolled for a second period of variable observation. After applying exclusion criteria for the present study, there were 342 participants remaining for analysis (Table 1). We included 1,851 diary periods for *C trachomatis*, 1,860 for *N gonorrhoeae*, and 1,864 for *T vaginalis* in our analysis. Participants contributed an average of 5.6 (SD $\pm$ 3.0) diary periods per person, with a range of 1–14. Median length of follow-up for both observation periods for the 342 participants was 42.2 months (95% CI = 39.9–45.0).

At the time of enrollment, 118 (34.5%) participants reported having had a DMPA shot in the previous 3 months. Three-fourths of these women ($n = 89/118$, 75.4%) stopped using DMPA at least once during their observation. Of the 224 women not using DMPA at enrollment, 87 (38.8%) of them initiated the use of DMPA during their period of observation. No differences were seen in median length of observation between these two groups of women, based on status of DMPA use at the time of enrollment (log-rank test $\chi^2 = 2.30$, $p > .12$).

The majority of the 342 participants included in the analysis were African American (89.8%) (Table 2). The average age of participants at the start of the diary periods was 16.0 (SD $\pm$ 1.34) years. Of the 342 participants, 154 (45.03%) had one or more infections with *C trachomatis*, *N gonorrhoeae*, or *T vaginalis* during the diary periods. Six hundred forty-two (33.81%) of the eligible diary periods had recorded DMPA use. There were 157 (8.5%) diary periods ending with a positive *C trachomatis* test, 65 (3.5%) diary periods ending with a positive *N gonorrhoeae* test, and 80 (4.3%) diary periods ending with a positive *T vaginalis* test.

Univariable analysis

In univariable analysis, there was no significant association between DMPA use during the current or previous 3-month period and incidence of infection with *C trachomatis*, *N gonorrhoeae*, or *T vaginalis* (Table 3). Age at the start of the diary period and number of total or unprotected sexual events in previous 3 months were not significantly associated with risk of infection. In contrast, the presence of a positive STI test at the start of the diary period and a larger number of both recent and lifetime sexual partners were each associated with an increased risk of *C trachomatis*, *N gonorrhoeae*, or *T vaginalis* infection.

Multivariable analysis

In multivariable analysis, there was no significant association between DMPA use in the current or previous 3-month period and incidence of *C trachomatis*, *N gonorrhoeae*, or *T vaginalis* infection, controlling for all other factors (Table 4). The number of total or unprotected sexual events during the diary period was not associated with risk of STI. Older age at the start of the diary

Table 3
Unadjusted odds ratios for acquisition of *C trachomatis*, *N gonorrhoeae*, or *T vaginalis* during the 3-month diary period

Variable	<i>C trachomatis</i> OR (95% CI)	<i>N gonorrhoeae</i> OR (95% CI)	<i>T vaginalis</i> OR (95% CI)
DMPA use in current diary period (yes/no)	.95 (.64–1.40)	1.22 (.69–2.16)	.65 (.35–1.19)
DMPA use in the previous 3-month period (yes/no)	1.08 (.70–1.67)	1.22 (.66–2.24)	.89 (.49–1.63)
Age at start of diary period	.94 (.86–1.02)	1.07 (.95–1.20)	1.10 (.98–1.22)
Positive STI test at start of diary period (yes/no)	3.08 (1.85–5.12)*	3.35 (1.12–10.01)***	4.92 (2.08–11.63)**
Number of partners in past 3 months	2.00 (1.59–2.53)*	2.40 (1.76–3.27)*	1.99 (1.44–2.74)*
Number of lifetime partners	1.05 (1.01–1.08)***	1.08 (1.02–1.13)***	1.07 (1.02–1.13)***
Number of sexual events in diary period	.98 (.96–1.00)	1.00 (.97–1.03)	1.00 (.97–1.03)
Number of unprotected sexual events in diary period	.98 (.95–1.00)	1.00 (.97–1.04)	1.00 (.97–1.03)

* $p < .0001$.

** $p < .001$.

*** $p < .05$.

Table 4Adjusted odds ratios for acquisition of *C trachomatis*, *N gonorrhoeae*, or *T vaginalis* during the 3-month diary period

Variable	<i>C trachomatis</i> OR (95% CI)	<i>N gonorrhoeae</i> OR (95% CI)	<i>T vaginalis</i> OR (95% CI)
DMPA use in current diary period (yes/no)	.76 (.45–1.31)	1.19 (.57–2.48)	.66 (.32–1.36)
DMPA use in previous 3-month period (yes/no)	1.17 (.69–1.96)	1.12 (.54–2.32)	1.04 (.52–2.08)
Age at start of diary period	.85 (.76–.96)***	.98 (.84–1.13)	.97 (.85–1.11)
Positive STI test at start of diary period (yes/no)	1.76 (.95–3.27)	2.92 (.98–8.66)	6.51 (2.90–14.63)*
Number of partners in past 3 months	2.10 (1.56–2.83)*	2.62 (1.81–3.79)*	1.91 (1.33–2.74)**
Number of lifetime partners	1.03 (.98–1.09)	1.02 (.97–1.09)	1.01 (.95–1.08)
Number of sexual events in diary period	.96 (.90–1.02)	.94 (.84–1.04)	1.00 (.94–1.07)
Number of unprotected sexual events in diary period	1.02 (.95–1.09)	1.06 (.94–1.18)	.98 (.91–1.05)

* $p < .0001$.** $p < .001$.*** $p < .05$.

period was a protective factor for infection with *C trachomatis*, but it showed no significant association with risk of either *N gonorrhoeae* or *T vaginalis* infection. A positive *T vaginalis* test at the start of the diary period was associated with a significantly increased risk of acquiring *T vaginalis* by the end of the diary period. However, the presence of a positive test for *C trachomatis* or *N gonorrhoeae* at the start of the diary period was not associated with increased risk of *C trachomatis* or *N gonorrhoeae* infection at the end of the diary period. The only factor significantly associated with an increased risk of contracting all three STIs was a greater number of sexual partners during the diary period. The number of lifetime partners was not significantly associated with the risk of any STI.

Discussion

This study considered the association between behavioral and biological risk factors and increased risk of acquisition of *C trachomatis*, *N gonorrhoeae*, and *T vaginalis* in an urban population of adolescent girls. A greater number of sexual partners over the 3 months since previous STI testing, younger age, and a history of a positive test for *T vaginalis* were independently associated with increased risk of STI infection.

We did not find an association between DMPA use and increased risk of STI. These findings are consistent with two [19,20] of the five prospective studies examining the association between STI and DMPA use. Of the three studies that found a positive association between DMPA use and *C trachomatis* infection, two were conducted in a different population: commercial sex workers in Malawi [16,17]. In the third study, Morrison and colleagues considered HIV-negative, predominately adult, women in the United States, and found significant association with DMPA use and total STI infection and *C trachomatis* infection alone [18]. However, the small number of infections—37 *C trachomatis* and 14 *N gonorrhoeae* for 45 infections in 1,988 evaluated segments—resulted in a wide confidence interval from 1.6 to 8.5. In contrast, our study included approximately four times the number of *C trachomatis* and *N gonorrhoeae* infections in a similar number of evaluated segments.

Our data demonstrated a strong association between having a positive *T vaginalis* test at the start of the diary period and acquisition of *T vaginalis* during that diary period. Because all subjects with a positive STI test at the start of a diary period received appropriate treatment, it is unlikely the ending positive test represents persistence of an inadequately treated infection. Instead, it may represent reinfection from an untreated partner.

Younger adolescents in our study were more likely to be infected with *C trachomatis* than older adolescents. Conversely, national STI surveillance data suggest that rates of *C trachomatis* infection peak between ages 18 and 20 years [25]; however, surveillance data are prone to screening and reporting biases. It is unclear whether the difference we observed is because of behavioral or biological variation between the age groups. Only one of the behavioral factors investigated in the study, which was the number of partners in the previous 3-month period, was significantly associated with acquisition of all three STIs. Total number of sexual events and number of unprotected sexual events in the previous 3-month period were not significantly associated with acquisition of *C trachomatis*, *N gonorrhoeae*, or *T vaginalis* infection. The lack of association between number of sexual events and STI acquisition may indicate that those without multiple partners in the past 3 months may have been in mutually monogamous relationships.

This study benefits from its large cohort and length of longitudinal follow-up, which contributed many STIs to our analysis. In addition, the use of daily dairies of sexual behaviors in conjunction with quarterly interviews helps reduce issues of recall bias. However, some important limitations of this study must be noted. One potential issue is that our study did not require laboratory documentation of clearance of an STI after a positive test. Instead, clearance was assumed to have occurred in patients who were prescribed appropriate treatment consistent with clinical care. Therefore, subsequent positive results were treated as independent infections, when it is possible these could represent persistent infections if patients did not take their prescribed course of treatment. Also, ours was an observational study and not a randomized controlled trial. As such, our findings could be affected by residual confounding.

Ultimately, we demonstrate that DMPA users and nonusers are at equal risk of acquiring *C trachomatis*, *N gonorrhoeae*, or *T vaginalis*. These data suggest that the variation in acquisition of STIs among sexually active adolescents in this population is because of sexual behaviors, such as number of sexual partners and age, rather than the presence or absence of hormonal contraception. Our data suggest that hormonal contraception should not be avoided in this population owing to concern for increased risk for acquisition of STIs. Instead, efforts to curb STI transmission among adolescents should focus on education regarding a reduced number of sexual partners.

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