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Initiation of Oral Contraceptives and Changes in Blood Pressure and BMI in Healthy Adolescents

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Abstract

Objectives—To describe changes in systolic blood pressure (SBP), diastolic blood pressure (DBP) and body mass index (BMI) associated with initiation and continued use of combined oral contraceptives (COCs) in healthy adolescents.

Study design—This observational, matched cohort study was conducted in two large health systems. Utilizing claims and electronic medical records, we identified adolescents 14-17.9 years of age initiating medium-dose COCs (containing 30 or 35 micrograms of ethinyl estradiol or equivalent and a progestin) between 7/1/07-12/31/09 with a baseline and at least one follow-up BP and BMI. COC-users were matched 1:2 by age, race/ethnicity and site to controls (COC-non-users). All BPs and BMIs recorded during outpatient visits starting 1 month prior to COC initiation (index date for controls), through 12/31/2010 were collected. Mixed model linear regression with random intercepts and slopes were then used to estimate changes in SBP, DBP and BMI over time.

Results—The 510 adolescent COC-users and 912 controls did not differ significantly by age, race/ethnicity, insurance, baseline SBP, DBP or BMI. After adjusting for baseline values, over a median of 18 months follow-up, COC-users had an decrease in SBP of 0.07 mmHG/month, and controls had an increase of 0.02 mmHG/month (p=.65). Similarly, DBP decreased by 0.007 mmHG/month in COC-users versus 0.006 mmHG/month in controls (p=.99). BMI increased by 0.04 (kg/m^2)/month in COC-users versus 0.025(kg/m^2)/month in controls (p=.09).

Conclusions—These data should provide reassurance to patients and providers regarding the lack of significant associations between COC-use and BMI or BP changes in adolescents.

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Keywords

contraception; hormones; cardiovascular risk

The combined oral contraceptive pill (COC), containing both estrogen and progestin, is the most common hormonal method utilized by sexually active adolescent females in the United States for preventing pregnancy. According to the 2006-2010 National Survey of Family Growth, 16% of all females 15-19 years of age and 33% of those ever sexually active reported current COC use.(1) Despite recent declines,(2) US teen pregnancy rates remain much higher than those in other developed nations.(3) Thus, increasing use of effective contraception such as COCs among sexually active youth is an important public health goal.

Although generally considered safe, initiation and continued use of COCs has been associated with small increases in office and ambulatory blood pressure (BP) in adult women.(4-6) Rarely, COC use has been associated with clinically significant BP changes. In secondary analyses of data from four clinical trials, among 1930 adult women prescribed a medium-dose COC, 2.5% developed new onset hypertension, and 0.67% experienced systolic blood pressure (SBP) increases of >20mm Hg. Of note, an additional 3.5% of women with elevated BP at baseline became normotensive while taking COCs.(7) Among 68,297 women in the Nurses' Health Study, current COC use was associated with an adjusted relative risk of 1.8 (95% CI 1.5-2.3) for developing incident hypertension.(8) In adult women with hypertension, COC use has been linked to increased risk for acute cardiovascular events including myocardial infarction and ischemic stroke.(9, 10)

Fewer studies have focused specifically on cardiovascular risk factors associated with COC use in adolescents and none have included longitudinal data. Several cross-sectional studies have reported associations between adolescent COC use and BP elevation. Among 120 adolescents in Belgium, COC-users had average SBP that was 4.6 mmHg higher than non-users.(11) A second study of more than 2000 adolescents in Germany reported that COC-use was associated with a small but statistically significant increase in systolic BP, with a mean of 115.2 mmHG in COC-users versus 113.6 in non-users.(12) A study of more than 1200 Australian youth reported that COC-users had higher SBP (3.3 mmHg) and diastolic blood pressure (DBP), (1.7 mmHG) than non-users.(13)

Adolescents who initiate COCs have the potential for long-term use. Thus even small increases in BP attributable to COCs could, over time, have significant clinical consequences. The current study was conducted to evaluate whether initiation and continued use of COCs is associated with changes in BP in adolescents. In addition, because weight and BP are strongly linked,(14, 15) and because fears of weight gain remain a barrier to contraception use in adolescents,(16, 17) the relation between COC use and BMI was also evaluated

METHODS

Patients were identified from two large integrated health care systems that offer comprehensive, confidential, reproductive health services for adolescents. Adolescents

14-17.9 years of age enrolled and receiving care at Kaiser Permanente Colorado or HealthPartners in Minnesota between July 1, 2007, and December 31, 2007, and initiating a medium dose COC (containing 30 or 35 micrograms of ethinyl estradiol or equivalent) were identified through automated review of administrative, electronic health record (EHR), and pharmacy claims data. The Institutional Review Board at HealthPartners Institute for Education and Research approved the study with ceding of oversight authority by the Kaiser Permanente Colorado Institutional Review Board.

COC initiation date was defined as the first pharmacy dispense date, following a period of at least 6 months during which any form of hormonal contraception was not dispensed. Subjects were eligible for inclusion if they had the following: (1) continuous insurance enrollment (including pharmacy coverage) starting at least 6 months prior to and continuing for 18 months following the COC initiation date; (2) baseline height, weight, and BP, recorded in the EHR within 1 month of the COC dispense date; and (3) At least one follow-up BP, height and weight recorded in the EHR at an outpatient medical visit during a period of continued COC-use.

COC-use periods were defined by accounting for the number and type of COC pill packs dispensed over time and recorded in pharmacy claims. Changes from one specific COC to another (such as from a norethindrone containing COC to a drosperinone containing COC) or to another form of hormonal contraception (such as injectable medroxyprogesterone) were censored at the change date. COC-users who did not refill their COCs were also censored when they reached a date at which <80% of days were covered. For example, a single pill pack was assigned as 28 days of medication. If by 35 days following the COC dispense date the subject had not filled a prescription for the same COC, she would be censored or only included as a COC-user up through day 35.

The control group consisted of COC-non-users, adolescents with continuous medical and pharmacy insurance coverage, at least 2 outpatient visits with BPs, heights, and weights, and no pharmacy records of prescriptions for hormonal contraceptives for the period 1/1/07-12/31/10.

Adolescents were excluded from both the COC-use and control groups for the following: 1) a diagnosis of hypertension or a diagnosis known to be a cause of secondary hypertension (includes renal, cardiac, endocrine and neurologic conditions); 2) treatment with stimulant, antipsychotic, or antihypertensive medication; 3) pregnancy at any time between 1/1/07-12/31/10.

Eligible adolescents initiating a COC (COC-users) were matched with controls (COC-non-users) in a 1:2 ratio using an optimal matching algorithm.(18) Match variables were age at index BP measurement (+/- 6 months), site, and race/ethnicity.

Outcomes

All BPs were recorded as part of outpatient medical visits and were measured by trained staff, predominantly using aneroid sphygmomanometers recalibrated as needed by bioengineering services. All measurements were conducted in the seated position with

selection of cuff size appropriate to arm size, consistent with national guidelines(19) and site-based protocols. In both health systems, weight was measured on a calibrated scale and height by stadiometer. Data on baseline and all follow-up BPs and BMIs starting 3 months prior to COC initiation (or index date) through 12/31/10 were taken directly from EHR using standardized data files, which include checks for biologically implausible values. BP percentiles were based on age-, sex-, and height-adjusted norms.(19) BMI percentiles were based on the year 2000 Centers for Disease Control and Prevention growth charts.(20)

Primary outcomes were estimated changes over time in SBP, DBP and BMI. In addition, we evaluated specific changes in SBP, DBP and BMI observed from baseline to 3 months, 6 months and 12 months following COC initiation (or index date for controls). As secondary outcomes we evaluated the proportion with clinically significant BP changes, defined as progression from a normotensive BP to a BP in the hypertensive range ($\geq 95^{th}$ percentile), as defined in the Fourth Report.(19) In addition, a clinically significant weight change was defined as an increase from baseline to follow-up measurement of ≥10 lbs.

Statistical Analyses

Baseline characteristics between COC-users and control adolescents were compared using Chi-Square tests. The timing of follow-up BPs, heights and weights was dependent on individual health seeking behaviors and varied by subject. Using T-tests, changes in SBP, DBP and BMI between COC-users and controls were compared among those with at least one follow-up measurement within the following time intervals of 3, 6, and 12 months. All BPs and BMIs recorded in the EHR at least 30 days following the COC dispense date for COC-users or the baseline measurements for controls were stratified as follows: 30-89 days = 3 months; 90-274 days = 6 months; 275-454 days = 12 months. For these analyses, subjects could contribute data to a single time interval, or multiple time intervals, depending on when BP and BMI were measured. Mixed model linear regression with random intercepts and slopes was then used to estimate changes in BP and BMI over time, while incorporating all available measurements and exact measurement dates for each subject. Given the size of the cohort, this study was powered to detect a standardized mean difference of 0.17 at 3 months, which equates to absolute differences in SBP of 1.9mm HG and in DBP of 1.4mmHG and an absolute difference in BMI of 0.8 kg/m^2 (α=.05, power 80%, two-tailed test) between groups. In an exploratory analysis we evaluated BP and BMI changes among COC-users with baseline elevated values.

RESULTS

Across the two study sites 2,434 adolescents initiating treatment with COCs between 7/1/07-12/31/09 were identified. Of those, 2,198 (90.3%) had a BP measured and 1,843 (76%) had BP, height and weight measured and recorded in the EHR within one month of the COC dispense date and had no comorbidities or medication use that would have an impact on BP. From this subset, 524 were excluded due to having no additional BP or BMI measurements and 801 were excluded due to discontinuing or changing type of hormonal contraception prior to subsequent BP measurement. An additional 5 were excluded due to short follow-up between the 1^{st} and 2^{nd} BP (≤30 days) and 6 due to delayed follow-up

between the 1st and 2nd BP (>547 days). Thus, our final cohort consisted of 510 COC-treated adolescents with at least 1 follow-up BP and BMI recorded during a period of continued use (20.9% of original sample). Their mean age was 16.4 years (SD=1.0), a majority were white non-Hispanic and privately insured (Table I). At baseline 25 (4.9%) had a SBP and/or DBP in the pre-hypertensive range and 19 (3.7%) in the hypertensive range. COC-users had BP and/or BMI measurements for a median of 18 months following initiation (range 1-21 months), with a median of 6 BP measurements and 6 BMI measurements.

For the control group, 24,809 adolescents with no pharmacy prescriptions for COCs between 1/1/07-12/31/10 were identified. Of these, 3,299 (13.3%) were excluded due to prescriptions for anti-hypertensive medications, medical conditions that may increase BP, or pregnancy. Of the 21,510 adolescents remaining, 11,502 (53.5%) had at least 2 BPs and 2 BMIs recorded in the EHR during the study period. Enrollment and drug coverage criteria reduced the final population of eligible unexposed adolescents to 5,958 (24.0% of initial sample).

Of these, 1,037 (17.4 %) were matched by age, site and race/ethnicity to COC users. An additional 19 were excluded due to too short follow-up and 106 due delayed follow-up between 1st and 2nd BP measurement. Thus, 912 controls were included in the final cohort. At baseline, 42 (4.6%) had a SBP and/or DBP in the pre-hypertensive range and 28 (3.1%) had a SBP and/or DBP in the hypertensive range. Their median observation period was 18 months (range 1-21 months)), including a median of 4 BP and 4 BMI measurements. The matched control cohort did not differ significantly from the COC-users across baseline characteristics (Table I).

Changes in BP

No statistically significant changes in systolic or diastolic BP were observed between COC-treated and control adolescents at 3, 6 and 12 months following COC initiation/index date. At 3 months, in a model adjusted for baseline BP, race and insurance type, SBP increased by 0.7 mmHG in COC-users and decreased by 0.4 mmHG in controls, and DBP increased by 0.4 mmHG in COC-users and decreased by 0.3 mmHG in controls. Additional changes at 6 and 12 months are in Table II.

In a mixed linear model, adjusting for baseline BP, race/ethnicity and insurance type, COC-users had a decrease in SBP of 0.07 mmHG/month, and control adolescents had an increase of 0.018 mmHG/month (p=.65). Using a similar model, DBP decreased by 0.007 mmHG/month in COC-users and 0.006 mmHG/month in unexposed (p=.99; Table II) At all time periods, progression to having a SBP or DBP in the hypertensive range was rare and did not differ between COC-users and non-users (Table III). Among the subset of COC-users with a baseline BP in the pre-hypertensive or hypertensive range, at 3, 6 and 12 months follow-up the proportion with an incident SBP ≥95th percentile was 13%, 14% and 4%, respectively.

Changes in BMI

No statistically significant changes in BMI were observed between COC-users and control adolescents at 3, 6 and 12 months following COC initiation/index date. At 3 months, in a

model adjusted for baseline BMI, race, and insurance type, BMI increased by 0.1 kg/m^2 in COC-users, but there was no change in BMI among controls. Additional changes in BMI at 6 and 12 months are shown in Table II.

In a mixed linear model, adjusting for baseline BMI, race/ethnicity and insurance type, COC-users had a BMI increase of 0.039 (kg/m^2)/month, and control adolescents had an increase of 0.025 (kg/m^2)/month (p=.09). Similarly, at 3, 6 and 12-months, COC-use was not associated with a statistically significant weight gain of 10lbs or greater (Table III). Among the subset of adolescent COC-users with a BMI ≥95th percentile at baseline, at 3, 6 and 12 months follow-up the proportion with a weight gain of ≥10lbs was 5%, 15% and 30%, respectively.

DISCUSSION

In studies of adult women, COCs have been associated with mild BP increases, and among women with hypertension COCs have been correlated with increases in cardiovascular morbidity.(4-7, 9) In this retrospective, observational matched cohort study of adolescents, initiation and continued use of COCs were not associated with statistically significant or clinically meaningful changes in weight or blood pressure.

To date, few studies have specifically evaluated cardiovascular effects of COCs in adolescents and none have included longitudinal data from the point of COC initiation. Although recent cross-sectional studies found an association between COCs and mild BP elevations,(11, 13) these findings were not confirmed in our longitudinal cohort. Although compared with controls a slightly higher proportion of COC-users had an increase in weight of 10 or more pounds at 6 and 12 months, these differences were not statistically significant. In addition, the BMI at 12 months in COC-users was, on average, only 0.2 kg/m^2 higher than that among controls, a difference that was not clinically or statistically significant. Our findings regarding COC-use and BMI changes are consistent with prior studies.(21, 22)

A strength of this study was the use of ambulatory clinic populations from two large geographically diverse integrated health care delivery systems. As such, these findings represent outcomes from usual clinical practice and are likely to be generalizable to adolescents seeking contraceptive services in similar outpatient settings. Furthermore, the relatively large sample size afforded power to detect small increases in SBP, DBP or BMI associated with COC use.

An additional notable finding was that after excluding adolescents with potential secondary causes of hypertension, at 3, 6, and 12 months of follow-up, there were few incident BPs ≥ 95th percentile among either COC-users or control adolescents. This is consistent with prior work from our group (15) and highlights the generally low prevalence of hypertension in this age group.

There were some limitations to this study. First, the designation of COC-use was based on the health plan pharmacy dispensing. Thus, adolescents receiving COCs without a pharmacy claim, as could occur if dispensed at a school-based or Title × Family Planning Clinic, may have been misclassified as non-users. In addition, adolescents starting on a COC but

stopping treatment before they were due for a refill may have been misclassified as COC users during periods when they were not taking COCs. Together, these potential misclassifications would have biased our findings to the null.

Second, recent studies have highlighted that the effects of COCs on BP may vary not only by the amount of estrogen but also by progestin type. Drosperinone, a mild diuretic used in newer COCs, may reduce the effects of estrogen on renin and adolesterone. Recent studies have demonstrated that oral contraceptives containing drosperinone do not alter blood pressure.(23, 24) Of the 510 COC-treated adolescents in this study, less than 4% were taking a drosperinone containing COC. Thus, this study was underpowered to evaluate whether BP and BMI changes differed by type of progestin.

Third, adult studies have shown that subjects with baseline elevated BP are at increased risk for adverse events related to COC use(9). Although we did describe BP changes among adolescents with baseline BPs in the prehypertensive or hypertensive range, this study was unable to further study the effect of COC in hypertensive adolescents because only 3.3% of COC users and controls had a baseline BP $\geq 95^{th}$ percentile.

Finally, our study cohort was comprised of approximately 20% of the adolescents identified as initiating hormonal contraception over an 18-month period, and nearly 30% of adolescents initiating COCs with a baseline BP and BMI did not have an additional BP recorded in clinic. As adolescents are known to have high rates of COC-discontinuation and low rates of return for follow-up visits(25-28), this loss of study subjects is not surprising.

In summary, this longitudinal study shows that COC use in healthy adolescents is not associated with an increase in either BP or BMI. These results should provide reassurance for patients, providers and families regarding the safety of COCs, as currently prescribed in adolescents, for the outcomes studied.

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List of abbreviations

COC	combined oral contraceptive
BMI	body mass index
kg/m^2	kilograms per meter-squared
BP	blood pressure
SBP	systolic blood pressure
DBP	diastolic blood pressure
mmHG	millimeters mercury
EHR	electronic health record

Table I

Baseline characteristics of combined oral contraceptive (COC) users and matched controls (COC-non-users)

	COC-users N=510	Control adolescents N=912
Mean age (SD)	16.4 (1.0)	16.4 (1.0)
Race/ethnicity (%)		
Black	4.9	5.5
Hispanic	11.8	10.9
White	68.8	69.0
Other	4.9	3.7
Missing	9.6	10.9
Type of insurance (%)		
Private	94.7	95.6
Public	5.3	4.4
Baseline BMI (%)		
<85th percentile	77.8	75.3
85th- <95th	15.7	14.7
≥95th percentile	6.5	10.0
Baseline Systolic BP		
Mean BP mmHG (SD)	107.7 (10.6)	106.6 (11.1)
Pre-hypertensive (%)	2.6	2.3
Hypertensive (%)	3.1	2.2
Baseline Diastolic BP		
Mean BP mmHG (SD)	65.6 (8.0)	65.5 (8.0)
Pre-hypertensive (%)	3.3	2.6
Hypertensive (%)	0.8	1.5

p>0.05 for all baseline comparisons between COC-users and Control adolescents

Table II

Mean systolic BP, Diastolic BP, and BMI over time among COC-users and control adolescents, adjusted for baseline values, race and insurance status*

	N		Systolic BP (mm Hg)		Diastolic BP (mmHG)		BMI (kg/m^2)	
Time	COC	Control	COC	Control	COC	Control	COC	Control
Baseline	510	912	106.5	106.1	64.9	64.8	23.1	23.1
3 months	231	242	107.2	105.7	65.3	64.5	23.2	23.1
6 months	355	474	106.8	106.8	65.6	65.7	23.2	23.2
12 months	350	546	106.4	106.0	65.1	65.9	23.5	23.3
Slope (Δ/month)	510	912	-0.070	0.018	-0.007	-0.006	0.039	0.025

COC = combined oral contraceptive

*p>0.05 for all comparisons between COC-users and Controls.

Table III

Clinically significant changes in BP and BMI over time, adjusted for baseline values, race and insurance status

	COC	Control	p-value
3 months			
N*	225	237	
Incident Systolic BP ≥ 95th percentile	0.9%	2.1%	0.18
Incident Diastolic BP ≥ 95th percentile	0.4%	0%	0.89
Weight gain of ≥10 lbs	1.8%	0.4%	0.27
6 months			
N*	341	465	
Incident Systolic BP ≥ 95th percentile	2.6%	1.1%	0.12
Incident Diastolic BP ≥ 95th percentile	2.0%	0.9%	0.25
Weight gain of ≥10 lbs	5.4%	3.2%	0.09
12 months			
N*	341	535	
Incident Systolic BP ≥ 95th percentile	2.1%	1.5%	0.56
Incident Diastolic BP ≥ 95th percentile	0.9%	0.4%	0.43
Weight gain of ≥10 lbs	11.4%	8.7%	0.07

COC = combined oral contraceptive

* For evaluation of incident systolic or diastolic BP ≥ 95th percentile we excluded 11 adolescents with a baseline BP ≥ 95th percentile