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# Progestin-only contraceptive pill use among women in the United States

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#### Abstract

**Background**—Progestin-only contraceptive pills (POPs) offer a safe and effective contraceptive option, particularly for women at increased risk of venous thromboembolism. However, the prevalence of POP use among women in the United States is unknown.

**Study design**—We analyzed population-based data from 12,279 women ages 15-44 years in the National Survey of Family Growth. Data were collected continuously from 2006 to 2010 by inperson, computerized household interviews. Analyses describe POP use across sociodemographic and reproductive characteristics and thromboembolic risk profiles.

**Results**—Overall, 0.4% of all reproductive aged women in the U.S. currently use POPs. POP use was higher among parous, postpartum and breastfeeding women than their counterparts (all p-values<0.001). Women at higher risk of thromboembolism (older, obese, diabetic, or smoking women) had similar proportions of POP use as women without those risks.

**Conclusion**—POPs are rarely used by U.S. women. While data on chronic disease were limited, our results suggest relatively few women with increased risk of thromboembolism are considering POPs when choosing an oral contraceptive.

#### Keywords

progestin-only contraceptives; hormonal contraceptive pill; thromboembolism

#### 1. Introduction

Oral contraceptives (OCs) are used by over 10 million U.S. women [1]. Combined OCs (COC), which contain both estrogen and progestin, are highly effective and have an excellent safety profile [1,2]. However, estrogen-containing formulations have long been known to increase the risk of venous thromboembolic events (VTE) [3-7]. Estrogen dosages in contraceptive products have decreased dramatically over the last five decades and most

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OC users have few risk factors and low absolute risk of VTE [2]. Yet, women using COCs have a 2- to 6-fold greater relative risk of VTE compared to non-users [2,8].

For women with higher risk of VTE, even combined hormonal contraceptives with lower dosages of estrogen may be clinically relevant [2-7]. In particular, obesity, diabetes, and hypertension all increasingly affect U.S. women of reproductive-age [9-13]; pregnancy and tobacco use are additional risk factors for VTE [2]. For women at increased risk of VTE, progestin-only contraceptive methods have particular advantages [2-4]. Progestin-only pills (POPs) are believed to have similar effectiveness to COCs [2] and do not increase the risk of VTE [8], yet use of POPs by U.S. women has not been documented.

Using the most recent population-based data, we estimated the prevalence of POP use among U.S. women, including women with VTE risk factors.

#### 2. Materials and methods

Our sample included all women ages 15 to 44 years (n=12,279) who participated in the most recent National Survey of Family Growth (NSFG), a nationally representative survey conducted by the National Center for Health Statistics. The U.S. population-based survey collects information on family life, marriage and divorce, pregnancy, infertility, use of contraception, and men and women's health. Data were collected continuously between 2006 and 2010 via household, in-person interviews. African American and Hispanic women and adolescents and young adults 15 to 24 years were oversampled. The survey response rate was 77%. Further information about the design and sampling of the NSFG can be found at http://cdc.govnchs/nsfg.htm [14]. The Institutional Review Boards of Princeton University and the University of Pittsburgh approved this study.

We focused on a series of questions regarding contraceptive use and specifically OC use. Women were first asked during the interview whether they had ever used a contraceptive method. They were further asked the type of contraceptive method they used during the month of the interview as well as in the month prior to the interview. Women who reported having used OCs in the current or previous month were presented with a chart of 98 OCs commonly used in the U.S. and asked to identify the brand of pill from the chart that they currently or most recently used. If they were not able to identify the pill from the chart, they were asked to present their pill pack to the interviewer. The list included six available progestin-only pills (all of which contain 0.35 mg norethindrone): Camilla®, Errin® Micronor®, Nor-QD®, Jolivette® and Nora-BE®. We considered women who identified any of these six formulations as their method and who reported using the pill in the month they were interviewed to be current POP users.

We used descriptive statistics to describe the sample and provide estimates of the proportion of women using POPs overall and by type of POP. We provide a population estimate of POP use based upon the 2010 data from the U.S. Census Bureau's estimate of the population of women ages 15-44 years (N=62,374,964) [15]. We also estimated the proportion of women using COCs who are at risk of an unintended pregnancy (non-pregnant, non-sterile, sexually active women not trying to get pregnant) [1]. We further describe and compare the proportions of women currently using POPs in our sample across sociodemographic groups and by key health-related and reproductive characteristics using bivariate chi-square tests.

We also examine POP use among women with VTE risk factors according to the WHO and CDC medical eligibility criteria for hormonal contraceptive use [3,4]. Risk factors assessed by the NSFG included age 35 years, overweight (25-29.9kg/m<sup>2</sup>) or obese ( $30 \text{ kg/m}^2$ ) body mass index (BMI) (versus underweight <18.5 kg/m<sup>2</sup> or normal weight 18.5-24.9 kg/m<sup>2</sup> BMIs), non-gestational diabetes, cigarette smoking a pack per day or more (versus none or

less than a pack per day in the past year), and postpartum status (having delivered within the three months prior to the interview). Each of these risk factors alone do not restrict use of COCs (i.e., they are eligibility categories 1 or 2) [3,4]. However, in combination or in the setting of other VTE risk factors not assessed by the NSFG (e.g., hypertension or hyperlipidemia), these conditions preclude use of COCs (i.e., they are rated categories 3 or 4) [3,4]. Due to small sub-sample sizes, we were unable to examine POP use among women with multiple risk factors.

We report unweighted frequencies (n), but in all analyses weighted data were used to account for the complex, stratified sampling design of the survey; weighted proportions (%) and tests of significance were computed using the *svy* series of commands in Stata 11.0 (Stata Corporation, College Station, TX).

#### 3. Results

#### 3.1. Description of the sample

Sample characteristics are presented in Table 1. The mean ( $\pm$  standard deviation) age of participants (n=12,279) was 29  $\pm$  8 years. The majority of women identified their race/ ethnicity as white (62%). Over half the sample (52%) reported some college education. Nearly half of women (48%) resided in a sub-urban area; fewer in urban (32%) and rural (20%) communities. Forty-six percent of women reported incomes below 200% of the federal poverty level, although the majority (66%) were employed. Twenty-seven percent of women were uninsured at some point during the previous year. Over half had ever been married (53%) or cohabitated with a non-marital partner (53%). Most women (70%) reported one current sexual partner.

Nearly two-thirds (61%) of women reported a history of pregnancy and 55% had given birth to one or more children. Few women reported being pregnant at the time of their interview (4%) or having delivered in the prior three months (2%); 2% were currently breastfeeding. A history of a gynecological problem was reported by 30% of women, including problems with ovulation (17%), ovarian cysts (16%), uterine fibroids (6%) and endometriosis (5%).

A significant number of women had risk factors for VTE. Thirty-four percent of women were aged 35 years or older. Nearly a quarter (23%) reported being overweight (BMI 25-29.9) and 28% reported being obese (BMI 30). Tobacco use was reported by 26% of women; 8% smoked a pack or more per day. Only 2% of women reported a history of non-gestational diabetes; 4% reported gestational diabetes.

#### 3.2 Contraceptive and progestin-only pill use

Eighty-eight percent of women reported ever having used a contraceptive method and 73% reported having used OCs. Among the women with a contraceptive history (n=10,779), 20% (n=2,032) (18% of all women) reported OC use in the month of the interview and 21% (n=2,072) reported OC use in the prior month.

Of women currently using an OC (n=2,032), approximately 2% (n=57) identified a POP as their current contraceptive method (Table 2). Overall, 0.4% of all women surveyed (n=12,279) were current POP users. This, along with the 2010 Census Bureau's population estimate that there are 62,374,964 women ages 15-44 years in the United States, suggests that approximately 249,500 US women currently use POPs.

We further examined POP use among women at potential risk of pregnancy. When excluding pregnant women (n=516) or women who desire pregnancy and are therefore not using contraception (n=395), women with a history of surgical (n=1,857) or non-surgical

(n=203) sterility, those with no history of sexual intercourse (n=1,674) or no intercourse in the last 3 months (n=2,240), 0.7% of all women at risk of unintended pregnancy used POPs as their contraceptive method (n=53/7,660).

The proportions of women using POPs according to pill type are shown in Table 2. Among OC users (n=2,032), Micronor® was the most common POP used (0.8%), followed by Errin® (0.8%), Camilla® (0.4%), Nor-QD® (0.2%), Jolivette® (0.2%) and Nora-BE® (0.1%).

POP use was similar across sociodemographic groups (Table 3). POP use did not vary by reason for OC use (p=0.68) nor by the type of medical practice from which a woman had received birth control within the previous 12 months (p=0.68). However, POP use varied by location of residence (p=0.003); among OC users, rural women had higher proportions of POP use than urban and sub-urban women (5% rural versus 1% urban and 2% suburban). Women who had been married were more commonly POP users than never married women (4% versus 1%, p<0.001).

POP use varied by reproductive characteristics (Table 3). POP varied by parity (p<0.001) and age at menarche (p=0.02); use was higher among multiparous women (6% for >1 childbirths, 4% for 1 childbirth versus 1% for nulliparous) and women with a late age at menarche (6% for age 14 years and older versus 2% for 11-14 years and 3% for <11 years). POP use was higher among those with a history of ovarian cysts (4% versus 2%, p=0.03) and among postpartum women (32% versus 2%, p<0.001) as compared to their counterparts.

Finally, POP use by VTE risk factors is presented in Table 4. POP use varied by intensity of smoking (p=0.008); among women using OC, those who smoked a pack of cigarettes or more per day (5%) had higher POP use than women who smoked less than a pack per day (0.2%) or who did not smoke (3%). POP use was similar among women <35 versus 35 years of age (p=0.22), across BMI groups (p=0.37) and with or without a diagnosis of non-gestational diabetes (p=0.65).

#### 4. Discussion

This analysis of nationally-representative U.S. data indicates that despite the large number of US women using OCs, very few are currently using POPs. Most commonly, POPs are used in the postpartum period. Given women's higher risk of VTE immediately postpartum and the potential effects of estrogen on breast milk supply and infant development, it is prudent to avoid estrogen during this time [3,4,16,17]. In addition, women who smoke had higher proportions of POP use than nonsmokers. Though, women with other risk factors for VTE did not have higher proportions of POP use. Use of POPs among women with higher body weights and older age was similar to that of thinner and younger women. None of the OC-using women with a diagnosis of diabetes were using POPs. The American College of Obstetricians and Gynecologists (ACOG) suggests that obesity and the use of COCs are independent risk factors for venous thromboembolism and that obese women should avoid estrogen-containing contraceptives when possible alternative contraceptive options exist because of the increased risk [16]. However, other organizations have issued somewhat divergent guidelines, allowing the use of estrogen-containing contraceptives by obese women [3,18]. Similarly, although guidelines recommend that diabetic women with end organ damage avoid estrogen, use of estrogen by women who have had diabetes for only a short period of time is considered acceptable [3,4]

Additionally, many clinicians remain concerned that POPs are less tolerated and therefore less effective than estrogen-containing contraceptives [19]. However, studies have reported similar satisfaction and continuation rates for women who used POPs or COCs [19-21].

Recommendations for specific use of POPs, such as stringent daily timing (POPs should be taken at the same time daily) and missed or late pills rules (back-up contraception is recommended for pills taken more than 3 h late), may also play an important role in clinicians perceptions of POPs and ultimately hinder their provision [22]. In Northern Europe and other regions, availability of POP formulations which more consistently suppress ovulation and contribute to less irregular bleeding (such as 0.075mg desogestrel) than formulations available in the U.S., may help explain their more widespread use in these settings [23,24]. The inconsistency around opinions and practices of prescribing and using POPs as well as women's access to different formulations highlights the need for further study of the comparative acceptability and effectiveness of POPs and COCs for women in the U.S. and abroad.

This study has a number of limitations, in particular, the lack of data on end-organ disease among diabetics, hypertension, hyperlipidemia or other relative contraindications to estrogen use. More broadly, these data do not make clear the full context in which women were choosing to use COC and/or POPs. The NSFG distinguishes pill type only with a single question about the OC currently used. Thus, we were unable to examine women's past use of POPs or COCs separately, pill switching, or POP dissatisfaction, which could have provided insight into the circumstances in which women chose or discontinued POPs within their contraceptive histories. It is possible that we were unable to fully disentangle relationships between BMI and race/ethnic characteristics, which may interact with age at menarche and other characteristics to contribute different rates of POP use [17,25]. Unfortunately, our sample of POP users was limited, precluding examination of the effects of multiple risk factors for VTE, multivariate analysis and our ability to identify the true determinants of POP use.

In conclusion, very few women in the U.S. use POPs. Further study of the basis for OC selection is needed, especially for women with chronic conditions that increase risk of VTE. A better understanding of situational factors and contraceptive experiences that contribute to women's use or nonuse of POPs may help identify areas for counseling and intervention to promote POPs for women who prefer OCs to more highly effective reversible contraceptive methods such as intrauterine devices and implants.

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#### Table 1

Sociodemographic, reproductive and health-related characteristics of the sample

U.S. women ages 15-44 years (n=12,279)	n	%
Age group, years		<u> </u>
15-24	4,382	34
25-34	4,413	32
35-39	1,798	17
40	1,686	17
Race/ethnicity		
Hispanic	2,723	17
White	6,301	62
Black	2,535	15
Other	720	6
Education level		
<high diploma<="" school="" td=""><td>1,878</td><td>13</td></high>	1,878	13
High school diploma or GED	2,557	21
Any college	5,884	52
Still in high school	1,960	14
Residence		
Urban	5,145	20
Suburban	5,296	32
Rural	1,838	48
Employment status		
Employed	7,701	66
Unemployed	723	5
In school	1,298	10
At home/other	2,557	19
Poverty level		
<200% federal poverty level	6,355	46
>200% federal poverty level	5,924	54
Insurance status		
Fully insured last year	8,700	73
Uninsured during last year	2,714	27
Marital history		
Ever married	5,534	47
Never married	6,745	53
Cohabitation history		
Ever cohabitated	6,450	52

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U.S. women ages 15-44 years (n=12,279)	n	%
Never cohabitated	5,829	48
Age at menarche, years		
< 11	1,166	8
11-14	9,818	82
> 14	1,295	10
Parity, number of childbirths		
0	5,596	45
1	2,214	16
>1	4,469	39
Postpartum 3 months		
Yes	253	2
No	12,026	98
Breastfeeding status		
Currently breastfeeding	266	2
Not breastfeeding	12,013	98
History of gynecological problems <sup><math>a</math></sup>		
Yes	8,901	71
No	3,378	29
History of ovarian cysts		
Yes	1,829	16
No	10,450	84
Gestational diabetes diagnosis		
Yes	413	4
No	11,866	96
Non-gestational diabetes diagnosis		
Yes	237	2
No	12,042	98
Body mass index		
Underweight, BMI <18.5 kg/m <sup>2</sup>	364	3
Normal weight, BMI 18.5-24.9 kg/m <sup>2</sup>	5,088	46
Overweight, BMI 25-29.9 kg/m <sup>2</sup>	2,732	23
Obese, BMI 30 kg/m <sup>2</sup>	3,314	28
History of smoking in last year		
None	9,090	74
< Pack of cigarettes per day	2,246	18
Pack of cigarettes per day	889	8

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Results are presented as frequencies (n) and weighted percentages (%).

<sup>a</sup>Gynecological problems may include ovulation problems, ovarian cysts, uterine fibroids or endometriosis.

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# Table 2

Progestin-only contraceptive pill use among women ages 15 to 44 years in the United States

	All women	n (n=12,279)	Women at risk of p	* regnancy (n=7,660)	Oral contraceptive users (n=2,032)	Progestin-only pill users (n=57)
	u	%	u	%	0%	%
Progestin-only pill use	57	0.4	53	2.0	2.0%	100
By pill brand						
Micronor®	21	0.2	19	0.2	0.8	35
Errin®	13	0.1	13	0.2	0.8	31
Camilla®	6	0.07	8	60.0	0.4	15
Nor-QD®	7	0.04	7	0.06	0.2	8
Jolivette®	5	0.03	4	0.04	0.2	L
Nora-BE®	2	0.02	2	0.03	0.1	4
Results are presented as fr	n) seinenne	) and weighted	nercentages (%)			

ages are pre \* Women at risk of pregnancy excludes currently pregnant women (n=516) or women not using contraception in order to get pregnant (n=395), women with no history of sexual intercourse (n=1,674) or intercourse in the last 3 months (n=2,240), and women with a history of surgical (n=1,857) or non-surgical sterility (n=203). Women with multiple exclusion criteria were excluded once from sample estimate.

#### Table 3

Progestin-only contraceptive pill use among selected groups of U.S. women using oral contraceptives

Oral contraceptive using women ages 15-44 years (n=2,032)	Pro	Progestin-only pill use (n=57, 2%)		
	n	%	POP versus COC use *p-value	
Age group, years			0.08	
15-24 (n=902)	17	2		
25-34 (n=825)	27	3		
35-39 (n=231)	6	2		
40(n=143)	8	6		
Race/ethnicity	1		0.73	
Hispanic (n=319)	6	2		
White (n=1,354)	44	3		
Black (n=253)	5	1		
Other (n=92)	2	2		
Education level			0.33	
< High school diploma (n=146)	3	3		
High school diploma or GED (n=306)	11	4		
Any college (n=1,294)	41	2		
Still in high school (n=272)	2	1		
Residence	1		0.003	
Urban (n=759)	17	1		
Suburban (n=915)	22	2		
Rural (n=344)	18	5		
Employment status			0.49	
Employed (n=1,457)	39	2		
Unemployed (n=80)	1	1		
In school (n=216)	6	2		
At home/other (n=247)	11	4		
Poverty level	1		0.36	
< 200% federal poverty level (n=769)	32	2		
200% federal poverty level (n=1,249)	25	3		
Insurance status			0.37	
Fully insured last year (n=1,578)	42	2		
Uninsured anytime during last year (n=440)	15	3		
Marital history			0.001	
Ever married (n=772)	36	4		
Never married (n=1,246)	21	1		

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Oral contraceptive using women ages 15-44 years (n=2,032)	Pro	gestin	-only pill use (n=57, 2%)
Age at menarche, years			0.02
<11(n=175)	4	3	
11-14 (n=1,636)	44	2	
> 14 (n=207)	9	6	
Parity, number of childbirths			<0.001
0 (n=1,278)	16	1	
1 (n=332)	19	4	
> 1 (n=408)	22	6	
Breastfeeding status			<0.001
Currently breastfeeding (n=30)	17	69	
Not breastfeeding (n=1988)	40	2	
History of gynecological problems <sup>a</sup>			0.68
Yes (n=543)	16	3	
No (n=1,475)	41	2	
History of ovarian cysts			0.03
Yes (n=288)	13	4	
No (n=1,728)	44	2	
History of gestational diabetes diagnosis			0.12
Yes (n=53)	3	6	
No (n=1965)	54	2	
Reason for using oral contraceptives			0.68
Birth control (n=811)	34	3	
Acne (n=63)	1	1	
Pre/Menstrual symptoms (n=282)	4	2	
Endometriosis (n=33)	1	2	
Regulate menstrual cycle (613)	12	2	
Other (n=214)	5	2	
Medical practice where birth control method received within last year	47	3	0.68
Private practice/HMO/employer-based (n=1,469)	5	1	
Community/public health clinic (n=231)	5	2	
Family planning clinic/Planned Parenthood (n=206)	0	0	
School-based health clinic (n=40)	0	0	
Hospital/urgent care center (n=12)			
Somewhere else (n=7)	0	0	

Results are presented as frequencies (n) and weighted percentages (%) of progestin-only pill use among women reporting oral contraceptive use in the month of interview, by sociodemographic characteristics.

\*P-value from chi-square test comparing progestin-only pill (POP) use versus combined estrogen and progestin oral contraceptive pill (COC) use across sociodemographic and reproductive characteristics.

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 $^{a}$ Gynecological problems may include ovulation problems, ovarian cysts, uterine fibroids or endometriosis.

#### Table 4

Progestin-only contraceptive pill use among women with risk factors for venous thromboembolism

Oral contraceptive using women ages 15-44 years (n=2,032)	Pro	Progestin-only pill use (n=57, 2%)		
	n	%	POP versus COC use *p-value	
Postpartum 3 months			<0.001	
Yes (n=24)	5	32		
No (n=1,994)	52	2		
History of smoking in last year			0.008	
None (n=1,611)	7	3		
< Pack of cigarettes per day (n=318)	2	0.2		
Pack of cigarettes per day (n=85)	5	5		
Older age, years			0.22	
Women aged 35 (n=367)	14	3		
Women aged < 35 (n=1,651)	43	2		
Body mass index			0.37	
Underweight, BMI <18.5 kg/m <sup>2</sup> (n=59)	1	1		
Normal weight, BMI 18.5-24.9 kg/m <sup>2</sup> (n=1,052)	27	2		
Overweight, BMI 25-29.9 kg/m <sup>2</sup> (n=436)	15	3		
Obese, BMI 30 kg/m <sup>2</sup> (n=444)	14	3		
Non-gestational diabetes			0.65	
Yes (n=13)	0	0		
No (n=2005)	57	2		

Results are presented as frequencies (n) and weighted percentages (%) of progestin-only pill use among women reporting oral contraceptive use in the month of interview, by venous thromboembolism risk factors.

\*P-value from chi-square test comparing progestin-only pill (POP) use versus combined estrogen and progestin oral contraceptive pill (COC) use across risk factors.