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Venous Thromboembolism Among Women Initiating Depot Medroxyprogesterone Acetate Immediately Postpartum

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Abstract

OBJECTIVE: To estimate the absolute and relative risk of venous thromboembolism (VTE) among women who initiate depot medroxyprogesterone acetate (DMPA) immediately postpartum compared with those who do not initiate hormonal contraception.

METHODS: The IBM MarketScan Commercial Claims and Encounters databases were used to identify delivery hospitalizations among women aged 15–44 years during 2005 through 2014. Diagnosis, procedure, and drug codes were used to identify contraception, VTE, and potential confounding chronic or pregnancy-related conditions. Women who initiated DMPA during days 0 through 7 postpartum were compared with women who did not initiate hormonal contraception during days 0 through 7 postpartum. Women were followed from date of delivery through 12 weeks postpartum for the occurrence of VTE, with censoring at hormonal contraception initiation or prescription, hysterectomy, sterilization, or inpatient death. The incidence rate of VTE and 95% CIs were calculated within each group and the incidence rate ratio was calculated comparing the two groups.

RESULTS: The unadjusted VTE incidence rate through 12 weeks postpartum was 0.42/10,000 women-days in the immediate postpartum DMPA group (34 events among 11,159 women contributing 805,999 days of follow-up) and 0.15/10,000 women-days in the control group (3,107 events among 3,102,011 women contributing 206,180,811 days of follow-up). The incidence rate ratio for VTE was 2.87 (95% CI 2.05–4.03) among women in the immediate postpartum DMPA group compared with women in the control group, adjusting for age alone. After adjusting for age

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and pregnancy-related and chronic conditions, the adjusted incidence rate ratio for VTE was 1.94 (95% CI 1.38–2.72) among women in the immediate postpartum DMPA group compared with women in the control group.

CONCLUSION: Initiation of DMPA immediately postpartum is associated with a low incidence but an increased relative risk of VTE compared with nonuse of hormonal contraception.

The immediate postpartum period is an ideal time to consider initiation of contraception because women have access to healthcare, are not pregnant, and may not follow up for postpartum visits. Initiating contraception immediately after delivery may reduce the risk of unintended pregnancies and short birth intervals, both of which have been associated with negative health outcomes.[1–3] Depot medroxyprogesterone acetate (DMPA) is effective, well-tolerated and is generally considered safe for use by postpartum women, including those who are breastfeeding.[4] In addition, it has the advantage of effectiveness for 12 weeks, allowing a bridge to long-acting or permanent methods for women who desire but are unable to receive those methods immediately postpartum because of logistical, financial, or other barriers.

An important concern for postpartum women is whether exposure to hormonal contraceptives might increase the risk of thrombosis. Depot medroxyprogesterone acetate has been associated with increased odds of venous thromboembolism (VTE) compared with nonuse, among the general population of women and women with certain risk factors for VTE, such as smoking, thrombogenic mutations, and diabetes.[5–8] Because postpartum women are at elevated risk of VTE compared with nonpregnant, nonpostpartum women of reproductive age, particularly within the first week postpartum, any further elevation in risk with DMPA use is of potential concern.[9,10] The objective of this study was to estimate the absolute and relative risk of VTE through 12 weeks postpartum among women who initiate DMPA immediately postpartum (up to 7 days postpartum) compared with those who do not initiate hormonal contraception.

METHODS

This analysis used the IBM MarketScan Commercial Claims and Encounters databases, which contain individual-level health care claims information from employers, health plans, and hospitals. The databases include linked information on health care services used in inpatient and outpatient settings as well as filled outpatient prescription drug claims. The databases undergo many steps to enhance data quality, including checking reasonableness of data against norms, checking validity of diagnosis and procedure codes against possible valid values and flagging improper coding for improvement.[11] Because the data are deidentified, the Centers for Disease Control and Prevention deemed this study to be research not involving human subjects and therefore did not need review by an institutional review board.

We identified women ages 15–44 with delivery hospitalizations during 2005 through 2014 (Fig. 1). International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Diagnosis Related Group, and Current Procedural Terminology (CPT) codes were used to identify delivery hospitalizations, and the date of first report of delivery

diagnoses or procedures was considered day 0 (Table 1). We included only women who were continuously enrolled from 12 months before through 12 weeks after delivery and who had information on outpatient pharmaceutical claims. For women who had multiple deliveries during the time period, only the first delivery was included. We excluded women with deliveries after September 30, 2014, to allow for 12 weeks of follow up for all women. We excluded women with ICD-9-CM codes indicating abortion, ectopic pregnancy, molar pregnancy, and other abnormal products of conception. We also excluded women who were prescribed anticoagulants during the 6 months before the delivery hospitalization because these women likely represent a group with a different baseline VTE risk, such as those with a previous VTE or thrombophilia. To assess whether we had identified all women with a previous VTE, we additionally examined women with VTE codes during the 12 months before delivery, and all of these women were prescribed anticoagulants during the 6 months before delivery hospitalization and were therefore excluded from analyses.

Contraceptive methods were identified using ICD-9-CM, CPT, National Drug Code or Healthcare Common Procedure Coding System codes. The exposed group was comprised of women who initiated DMPA within the first 7 days postpartum. Because National Drug Code and Healthcare Common Procedure Coding System codes were not available for the inpatient setting, DMPA initiation in the hospital required ICD-9-CM procedure code 99.24 (injection of other hormone) plus an ICD-9-CM diagnosis code indicating contraceptive management (Table 1). The control group of interest was women using nonhormonal contraception (ie, copper intrauterine device) or no contraceptives in the immediate postpartum period.

Our outcome of interest was VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE) as identified by ICD-9-CM codes (Table 1). The date of VTE diagnosis was assigned as the date of first reported DVT or PE code after delivery. For VTEs identified in outpatient claims only, we required a diagnosis code plus a filled anticoagulant prescription claim, in an attempt to minimize misclassification of women who were assessed for VTE but ultimately ruled out.[12,13] For inpatient VTEs, we required diagnosis codes only because diagnoses are assigned at the time of hospital discharge and are therefore likely to be confirmed diagnoses.[13]

Women were followed through 12 weeks postpartum, or were censored at the earliest occurrence of VTE, hormonal contraception initiation or prescription (including DMPA after 7 days postpartum), female sterilization, hysterectomy, or inpatient death. Sterilization and hysterectomy were identified using ICD-9 or CPT codes if they appeared once in either inpatient or outpatient claims.

We considered age and certain chronic medical conditions that have been found to be significant risk factors for VTE during pregnancy as potential confounders.[14,15] Age at delivery was categorized into five groups (15–24, 25–29, 30–34, 35–39, and 40–44 years). Chronic medical conditions were identified by ICD-9-CM codes during the 12 months before delivery and included pregestational diabetes, chronic hypertension, obesity, and smoking. Cardiovascular conditions, cerebrovascular disorders, and heart failure were identified by ICD-9-CM codes reported during 12 months before delivery through 12

weeks postpartum, given that these conditions could be pre-existing or pregnancy-related. Outpatient diagnoses were considered valid only if the codes appeared two or more times at least 30 days apart. Inpatient diagnoses were considered valid even if they appeared only once.

We also considered several pregnancy-related conditions and complications as potential confounders, including cesarean delivery, gestational hypertension, preeclampsia, eclampsia, multiple birth, anemia, antepartum hemorrhage, postpartum hemorrhage, postpartum infection, intrauterine fetal demise, blood transfusion, pulmonary edema, adult respiratory distress syndrome, disseminated intravascular coagulation, obstetric shock, sepsis, ventilation, and peripartum cardiomyopathy. These conditions were identified by ICD-9-CM codes or CPT codes reported within 40 weeks before delivery through 12 weeks postpartum. Outpatient diagnoses were considered valid only if the codes appeared two or more times. Outpatient procedures (transfusion or ventilation) were considered valid if reported only once. Inpatient diagnoses were considered valid if they appeared only once.

The percent distributions of risk factors for women in the DMPA group and women in the control group were calculated and compared using a Chi-square test. Incidence rates of VTE through 12 weeks postpartum for women in the immediate postpartum DMPA and control groups were calculated as the number of VTEs divided by women-days of follow up. The denominator of women-days was used to account for different lengths of follow-up contributed by women who were censored before 12 weeks postpartum. A Poisson regression model was used to estimate the incidence rate ratio and 95% CI for VTE among women exposed to immediate postpartum DMPA compared with women in the control group. The incidence rate ratio was adjusted for age group alone (ages 15–24, 25–29, 30–34, 35–39, and 40–44) and additionally for age group and risk factors that were found to be associated with DMPA use in our bivariate analyses and with VTE risk in previous studies.[10,16,17]

A subgroup analysis was conducted among women less than 35 years of age and without any of the considered risk factors to assess idiopathic VTE among low-risk women. SAS 9.4 was used for all analyses. Analyses were independently conducted by two coauthors and any differences were adjudicated by discussion.

RESULTS

After applying exclusions, there were 11,159 women who initiated DMPA during the first 7 days postpartum and 3,102,011 women who did not (Table 2). Women who initiated immediate postpartum DMPA were younger than women in the control group; the proportion of women ages 15–24 was 29% in the immediate postpartum DMPA group and 17% in the control group ($P<.001$). Women who initiated immediate postpartum DMPA were more likely than women in the control group to have pregestational diabetes (2.6% vs 2.0%), to have chronic hypertension (5.8% vs 4.1%), to be obese (3.4% vs 2.5%), and to be smokers (3.6% vs 1.6%) ($P<.001$ for all comparisons). Women in the DMPA group were less likely than women in the control group to have experienced cesarean delivery (10.3% vs 14.7%) and were more likely to have experienced pregnancy or postpartum complications

including hypertensive disorders (ie, gestational hypertension, preeclampsia, or eclampsia) (16.2% vs 11.7%), multiple birth (5.2% vs 2.7%), anemia (16.7% vs 11.2%), antepartum hemorrhage (9.0% vs 4.6%), postpartum hemorrhage (4.4% vs 2.4%), postpartum infection (1.8% vs 0.7%), intrauterine fetal demise (0.9% vs 0.4%), and other severe complications (2.5% vs 1.6%) ($P<.001$ for all comparisons).

Venous thromboembolism occurred among 34 women (contributing 805,999 days of follow-up) in the immediate postpartum DMPA group and 3,107 women (contributing 206,180,811 days of follow-up) in the control group (Table 3). The unadjusted VTE incidence rate through 12 weeks postpartum was 0.42/10,000 women-days (95% CI 0.30–0.59) for women in the immediate postpartum DMPA group and 0.15/10,000 women-days (95% CI 0.15–0.16) for women in the control group. When adjusting for age, the incidence rate ratio for VTE was 2.87 (95% CI 2.05–4.03) among women in the immediate postpartum DMPA group compared with women in the control group. After adjusting for age and all other considered risk factors, the incidence rate ratio for VTE was 1.94 (95% CI 1.38–2.72).

In a subgroup analysis including women younger than 35 years without any of the considered risk factors, the VTE incidence rate was 0.15/10,000 women-days (95% CI 0.06–0.37) for women in the immediate postpartum DMPA group and 0.06/10,000 women-days (95% CI 0.05–0.06) for women in the control group. The age-adjusted incidence rate ratio of VTE for women in the immediate postpartum DMPA group compared with women in the control group was 2.82 (95% CI 1.17–6.81).

DISCUSSION

This analysis found that initiation of DMPA in the first week postpartum was associated with an increased incidence rate ratio for VTE relative to nonuse of hormonal methods. The subgroup analysis among women without VTE risk factors demonstrated similar results. Although we found an increased incidence rate ratio, it is important to note the absolute incidence rate for women in the immediate postpartum DMPA group was low (0.42/10,000 women-days), and was even lower when examining younger women without risk factors (0.15/10,000 women-days).

Our findings are similar to studies looking at VTE risk among women in the general population using DMPA (odds ratios 2.2–3.0 compared with nonhormonal users).[5,6,8] Although little is known about risk of VTE with DMPA use in the immediate postpartum period, a few studies have examined VTE risk with DMPA use among women with other VTE risk factors.[18] These studies have found increased odds of VTE among women with factor V Leiden mutation, diabetes, or who smoke.[5–7] However, the small numbers and wide CIs in those studies limit interpretation, and it is unclear whether those results can be extrapolated to postpartum women. Little is known about VTE risk with use of other hormonal methods during the postpartum period. Although estrogen-containing methods are generally not recommended,[4] progestin-only methods other than DMPA have not been found to increase VTE risk.[18]

The mechanisms by which DMPA could potentially affect thrombosis are not well understood. Depot medroxyprogesterone acetate has been found to have varying effects on coagulation parameters; however, clinical effects are not clear.[19,20] In addition, it is not clear whether biological effects of progestins might interact with mechanisms related to postpartum thrombosis.

Although our study is strengthened by the large size of the MarketScan database, which allows for assessment of relatively rare events such as VTEs, the use of administrative data has several limitations. First, without access to drug codes in the inpatient setting, we identified DMPA initiated in the hospital using less specific diagnosis and procedure codes which may have led to misclassification of DMPA use. The frequency of DMPA initiation immediately postpartum in our study was lower than in other populations in the United States, although these studies included women who were largely minority, low income, and Medicaid users.[21,22] Second, because we were unable to verify VTE diagnoses with medical records, it is likely that some misclassification of VTEs occurred; however, we do not expect misclassification would be differential between groups. We attempted to minimize misclassification by requiring anticoagulation prescriptions for VTEs diagnosed in outpatient settings. Finally, there may have been misclassification of the factors that we controlled for in the analysis, such as obesity and smoking, and we were unable to examine certain factors unavailable in this administrative dataset such as race, ethnicity, immobility, and other demographic and socioeconomic characteristics; both limitations may have led to residual confounding. In a study of hospital discharge data, the validity of diagnostic codes for certain chronic conditions such as obesity, diabetes, and hypertension, was variable; however, the validity of pregnancy-related comorbidities, such as cesarean delivery, multiple gestation, hemorrhage, infection, and preeclampsia, was high.[23] The higher prevalence of most of the chronic conditions and pregnancy complications (except cesarean delivery) for women in the DMPA group indicates that this group might have been at higher risk for VTE regardless of contraceptive use. This may reflect preferential prescribing of DMPA (for example, over combined hormonal methods) for women at risk of VTE. Although we adjusted for the risk factors in the analysis, residual confounding may be present.

In conclusion, the increased relative risk of VTE with initiation of DMPA immediately postpartum observed in this analysis needs further study using additional data sources and different study populations. When counseling women about risks and benefits of postpartum contraception, it is important to discuss the low absolute risk of VTE even with use of DMPA and that the VTE risk associated with pregnancy is likely higher than any potential small risk associated with contraception. In addition, it is important to consider risks associated with short-interval pregnancies when discussing whether to initiate contraception immediately compared with delayed postpartum. Future research including comparison of risk with different hormonal contraceptive methods and risk throughout the postpartum period may help clarify this issue.

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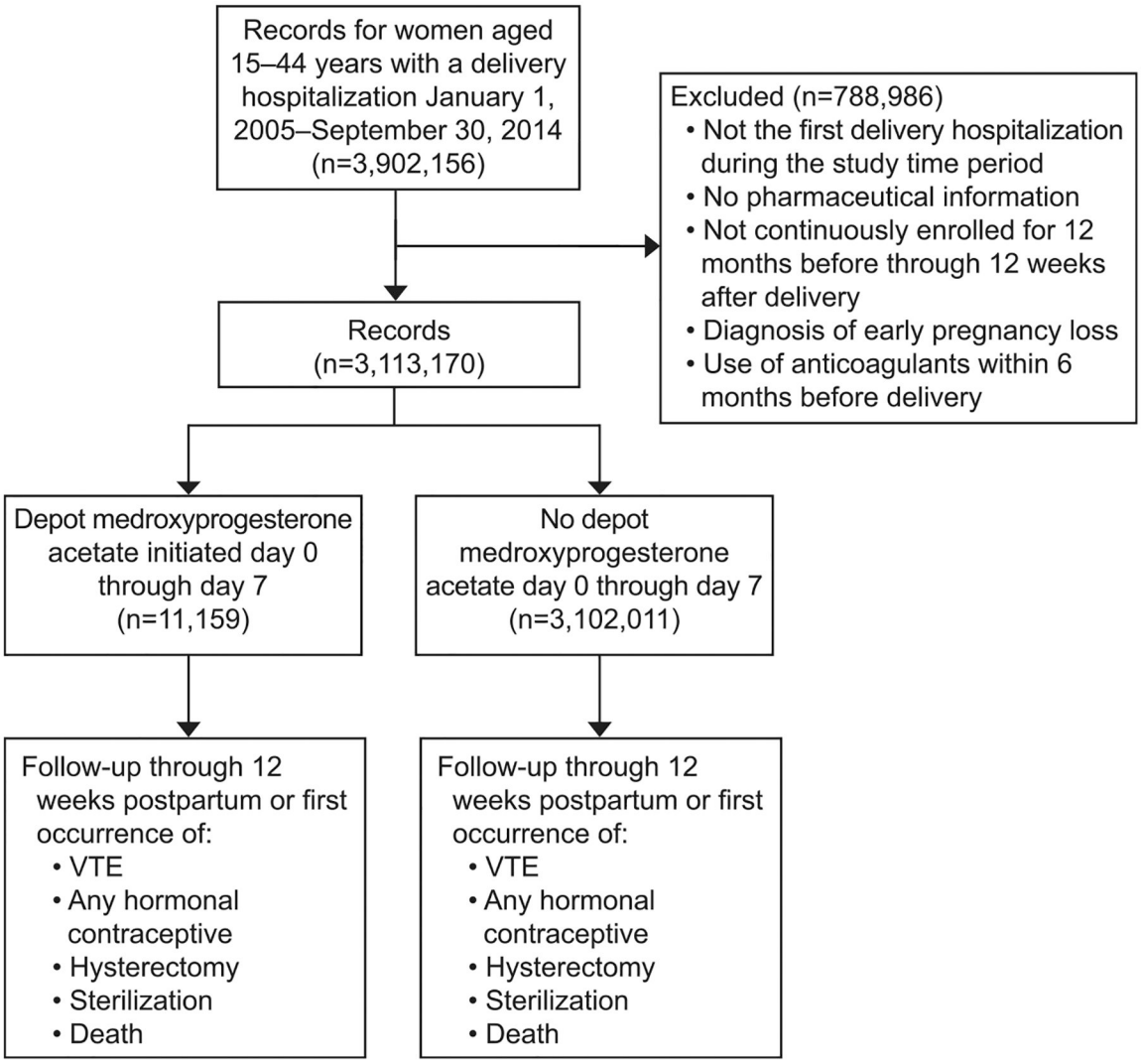

Fig. 1.

Categorization of potential participants by exclusion, exposure, and censoring event. VTE, venous thromboembolism.

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Table 1.

Codes Used to Idenify Delivery Hospitalizations, Initiation of Depot Medroxyprogesterone Acetate, and Venous Thromboembolism

Code Type	Code	Description
Deliveries		
ICD-9-CM diagnosis codes	V27.x	Outcome of delivery (all)
	650	Normal delivery
	669.7x	Cesarean delivery
ICD-9-CM procedure codes	74.0, 74.1, 74.2, 74.4, 74.99, 669.7x	Cesarean delivery
	72.0, 72.1, 72.21, 72.29, 72.31, 72.39	Low, mid, high forceps operation
	72.4	Forceps rotation of fetal head
	72.6	Forceps application to aftercoming head
	72.51, 72.52, 72.53, 72.54	Breech extraction
	72.71, 72.79	Vacuum extraction
	72.8	Other specified instrumental delivery
	72.9	Unspecified instrumental delivery
	73.22	Internal and combined version with extraction
	73.59	Other manually assisted delivery
	73.6	Episiotomy
CPT codes	59514	Cesarean delivery only, no postpartum care
	59620	Cesarean delivery only, after attempted vaginal delivery
	59409	Vaginal delivery only (with or without episiotomy, forceps, or both), no postpartum care
	59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy, forceps, or both)
DRG codes	2006 or before (370–375); after 2006 (765–768, 774,775)	Outcome of delivery (all)
DMPA		
ICD-9-CM diagnosis codes	V25.02	Initiation of other contraceptive method
	V25.04	Family planning
	V25.09	Counseling
	V25.40	Contraceptive surveillance, unspecified
	V25.49	Surveillance other contraceptives
	V25.8	Other contraceptive management
	V25.9	Unspecified contraceptive management

Code Type	Code	Description
ICD-9 procedure codes	99.24	Injection of other hormone
CPT codes	90772	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
HCPCS codes	J1050, J1051, J1055	Medroxyprogesterone acetate
NDC codes	00009074630, 00009074631, 00009074634, 00009074635, 00009470901, 00009470913, 00009737601, 00009737602, 00009737603, 00009737604, 00009737607, 00009737611, 00403504318, 00703680101, 00703680104, 00703681121, 23490585401, 54569370100, 54569490400, 54569552700, 54569561600, 54569621900, 54868361300, 54868410000, 54868410001, 54868525700, 55045350501, 55045394001, 59762453701, 59762453702, 59762453801, 59762453802, 59762453809	Medroxyprogesterone acetate
VTE		
ICD-9 diagnosis codes	671.3x, 671.4x, 671.5x, 671.9x, 451.1, 451.2, 451.9, 451.81, 453.1, 453.2, 453.40–453.42, 453.8, 453.9	DVT
	673.2x, 673.8x, 415.1	Pulmonary embolism
AHFS therapeutic class	39	Anticoagulants
	44	Thrombolytic agents, not elsewhere classified

ICD-9-CM, International Classification of Diseases, 9th Revision, Clinical Modification; CPT, Current Procedural Terminology; DRG, Diagnosis Related Group; DMPA, depot medroxyprogesterone acetate; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; VTE, venous thromboembolism; DVT, deep vein thrombosis; AHFS, American Hospital Formulary Service.

Table 2.

Characteristics of Women With Delivery Hospitalizations During 2005–2014, Stratified by Receipt of DMPA During Postpartum Days 0 Through 7

Condition*	DMPA Group	Control Group
Total	11,159	3,102,011
Age group (y)		
15–24	3,231 (29.0)	532,743 (17.2)
25–29	3,439 (30.8)	937,164 (30.2)
30–34	2,881 (25.8)	1,015,684 (32.7)
35–39	1,304 (11.7)	505,292 (16.3)
40–44	304 (2.7)	111,128 (3.6)
Chronic conditions		
Pregestational diabetes	288 (2.6)	60,731 (2.0)
Chronic hypertension	649 (5.8)	127,481 (4.1)
Obesity	375 (3.4)	75,911 (2.5)
Smoking	399 (3.6)	49,319 (1.6)
Pregnancy or postpartum conditions or complications		
Mode of delivery		
Vaginal	10,011 (89.7)	2,645,680 (85.3)
Cesarean	1,148 (10.3)	456,331 (14.7)
Gestational hypertension, preeclampsia, eclampsia	1,812 (16.2)	361,647 (11.7)
Multiple birth	581 (5.2)	83,317 (2.7)
Anemia	1,859 (16.7)	345,988 (11.2)
Antepartum hemorrhage	1,002 (9.0)	143,388 (4.6)
Postpartum hemorrhage	489 (4.4)	73,978 (2.4)
Postpartum infection	205 (1.8)	21,054 (0.7)
Intrauterine fetal demise	98 (0.9)	12,726 (0.4)
Other severe complications†	277 (2.5)	50,159 (1.6)

DMPA, depot medroxyprogesterone acetate.

Data are n (%).

*Chi-square $P<.001$ for difference in all conditions between DMPA group and control group.

† Includes: cardiovascular conditions, cerebrovascular disorders, heart failure, blood transfusion, pulmonary edema, adult respiratory distress syndrome, disseminated intravascular coagulation, obstetric shock, sepsis, ventilation, and peripartum cardiomyopathy.

Table 3.

Risk of VTE Through 12 Weeks Postpartum Among Women Who Received DMPA During Postpartum Week 1 Compared With Nonusers, 2005–2014

Group	Total No. of Women	Total No. of VTE	Total No. of Follow-up Days	VTE Incidence Rate/10,000 Women-Days (95% CI)	Incidence Rate Ratio (95% CI), Partially Adjusted*	Incidence Rate Ratio (95% CI), Fully Adjusted†
Immediate postpartum DMPA group	11,159	34	805,999	0.42 (0.30–0.59)	2.87 (2.05–4.03)	1.94 (1.38–2.72)
Control group	3,102,011	3,107	206,180,811	0.15 (0.15–0.16)	Ref	Ref

VTE, venous thromboembolism; DMPA, depot medroxyprogesterone acetate; Ref, reference.

Data are n, incidence rate (95% CI), or incidence rate ratio (95% CI).

*Adjusted for age group (15–24, 25–29, 30–34, 35–39, and 40–44 years).

†Adjusted for age group, pregestational diabetes, chronic hypertension, obesity, smoking, cesarean delivery, gestational hypertension, preeclampsia, eclampsia, multiple birth, anemia, antepartum hemorrhage, postpartum hemorrhage, postpartum infection, intrauterine fetal demise, and other severe complications.