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Oral Contraceptive Pills Are Not a Risk Factor for Deep Vein Thrombosis or Pulmonary Embolism After Arthroscopic Shoulder Surgery

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Abstract

Background: Worldwide, more than 100 million women between the ages of 15 and 49 years take oral contraceptive pills (OCPs). OCP use increases the risk of venous thromboembolism (VTE) through its primary drug, ethinylestradiol, which slows liver metabolism, promotes tissue retention, and ultimately favors fibrinolysis inhibition and thrombosis.

Purpose: To evaluate the effects of OCP use on VTE after arthroscopic shoulder surgery.

Study Design: Cohort study; Level of evidence, 3.

Methods: A large national payer database (PearlDiver) was queried for patients undergoing arthroscopic shoulder surgery. The incidence of VTE was evaluated in female patients taking OCPs and those not taking OCPs. A matched group was subsequently created to evaluate the incidence of VTE in similar patients with and without OCP use.

Results: A total of 57,727 patients underwent arthroscopic shoulder surgery from 2007 to 2016, and 26,365 patients (45.7%) were female. At the time of surgery, 924 female patients (3.5%) were taking OCPs. The incidence of vascular thrombosis was 0.57% (n = 328) after arthroscopic shoulder surgery, and there was no significant difference in the rate of vascular thrombosis in male or female patients (0.57% vs 0.57%, respectively; $P > .99$). The incidence of VTE in female patients taking and not taking OCPs was 0.22% and 0.57%, respectively ($P = .2$). In a matched-group analysis, no significant difference existed in VTE incidence between patients with versus without OCP use (0.22% vs 0.56%, respectively; $P = .2$). On multivariate analysis, hypertension (odds ratio [OR], 2.00; $P < .001$) and obesity (OR, 1.43; $P = .002$) were risk factors for VTE.

Conclusion: OCP use at the time of arthroscopic shoulder surgery is not associated with an increased risk of VTE. Obesity and hypertension are associated with a greater risk for thrombolic events, although the risk remains very low. Our findings suggest that patients taking OCPs should be managed according to the surgeon's standard prophylaxis protocol for arthroscopic shoulder surgery.

Keywords

oral contraceptives, shoulder arthroscopic surgery, deep vein thrombosis, complications

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Background: Worldwide, more than 100 million women between the ages of 15 and 49 years take oral contraceptive pills (OCPs). OCP use increases the risk of venous thromboembolism (VTE) through its primary drug, ethinylestradiol, which slows liver metabolism, promotes tissue retention, and ultimately favors fibrinolysis inhibition and thrombosis.

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Results: A total of 57,727 patients underwent arthroscopic shoulder surgery from 2007 to 2016, and 26,365 patients (45.7%) were female. At the time of surgery, 924 female patients (3.5%) were taking OCPs. The incidence of vascular thrombosis was 0.57% (n = 328) after arthroscopic shoulder surgery, and there was no significant difference in the rate of vascular thrombosis in male or female patients (0.57% vs 0.57%, respectively; $P > .99$). The incidence of VTE in female patients taking and not taking OCPs was 0.22% and 0.57%, respectively ($P = .2$). In a matched-group analysis, no significant difference existed in VTE incidence between patients with versus without OCP use (0.22% vs 0.56%, respectively; $P = .2$). On multivariate analysis, hypertension (odds ratio [OR], 2.00; $P < .001$) and obesity (OR, 1.43; $P = .002$) were risk factors for VTE.

Conclusion: OCP use at the time of arthroscopic shoulder surgery is not associated with an increased risk of VTE. Obesity and hypertension are associated with a greater risk for thrombolic events, although the risk remains very low. Our findings suggest that patients taking OCPs should be managed according to the surgeon's standard prophylaxis protocol for arthroscopic shoulder surgery.

Keywords: oral contraceptives; shoulder arthroscopic surgery; deep vein thrombosis; complications

Arthroscopic shoulder surgery is one of the most frequently performed orthopaedic procedures.[12] The procedure is generally considered to have a low risk for complications in general and particularly with regard to the development of vascular thrombosis.[4,6,10,20,22,25] While vascular thrombosis is the leading cause of morbidity and mortality after joint reconstruction,[1,21] there is significantly less information regarding the risk factors and implementation of preventive measures for venous thromboembolism (VTE; deep vein thrombosis [DVT] and/or pulmonary embolism [PE]) after arthroscopic shoulder surgery. The rate of VTE after arthroscopic shoulder surgery has been shown to range from 0.01% to 0.31%, while the rate of asymptomatic VTE is as high as 5.7%.[3,6,10,11,15,20]

Although symptomatic thromboembolic events are rare after shoulder surgery, these complications are attributed to 20% of hospital admissions within 30 days of arthroscopic shoulder surgery.[9] Because of the effect of readmissions on the health care system, it is imperative to identify risk factors that may contribute to postoperative adverse events.[9,16,19,22] History of cancer, blood disorders, history of tobacco use, operative time, and lateral positioning have

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been identified as potential risk factors for venous thrombosis after arthroscopic shoulder surgery.[2,4,8,13] A limited number of studies have investigated risk factors for the development of VTE after shoulder surgery, and to date, no study has investigated the use of oral contraceptive pills (OCPs) at the time of arthroscopic shoulder surgery.[5,20]

Worldwide, more than 100 million women between the ages of 15 and 49 years take OCPs.[17] OCP use increases the risk of VTE through its primary drug, ethinylestradiol, which slows liver metabolism, promotes tissue retention, and ultimately favors fibrinolysis inhibition and thrombosis.[17,23,24] The associated risk of OCP use and thrombolic events after orthopaedic procedures is unclear. With a large number of female patients undergoing arthroscopic shoulder surgery who may be on OCPs or hormone replacement therapy, it is of clinical importance to determine the impact of OCPs on thromboembolic complications.

The purpose of this investigation was to evaluate the relationship between OCPs and the rate of thromboembolic complications, including upper and lower extremity DVT and PE, after arthroscopic shoulder surgery utilizing a national insurer database. We hypothesized that patients taking OCPs at the time of surgery would be at a greater risk of developing postoperative vascular complications in comparison with patients not taking OCPs at the time of surgery.

METHODS

The PearlDiver patient records database was queried for Humana-insured patients from 2007 to 2016. This database contains deidentified information on more than 20 million patients in the United States. Patient demographics, hospitalization, diagnoses, procedures, and reimbursement are accessible from the database. All data can be accessed with International Classification of Diseases, 9th and 10th Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM, respectively) procedural codes and Current Procedural Terminology (CPT) codes. The accessed data represent procedures and diagnoses that were billed to the insurance company by the provider. PearlDiver documents prescription records based on the drug categorization, form, strength, and/or route of administration. Patients with a prescription record of OCPs at the time of surgery as identified by National Drug Codes were queried.

Patients who underwent isolated arthroscopic labral repair (CPT 29806), superior labral tear from anterior to posterior (SLAP) repair (CPT 29807), rotator cuff repair (CPT 29827), or glenohumeral debridement (CPT 29822 or 29823) were identified. Patients who underwent concomitant subacromial decompression, distal clavicle excision, debridement, or biceps tenodesis were included in the investigation, and those who underwent lysis of adhesions, manipulation under anesthesia, total shoulder arthroplasty, or open rotator cuff repair were excluded from the study population. Patients with a history of DVT or PE before the index procedure were identified via ICD-9 and ICD-10 diagnosis codes. These patients were also excluded, as a history of VTE is a well-established risk factor.[14] Patients who were previously diagnosed with a primary (ICD-9 289.81) or secondary (ICD-9 289.82) hypercoagulable state or unspecific coagulation disorder (ICD-9 286.9) were also excluded from this study. Additionally, patients who underwent subsequent contralateral or ipsilateral arthroscopic shoulder surgery were counted only once with their index procedure.

Before matching, multivariate regression was performed to identify independent risk factors for developing vascular thrombosis in female patients who underwent arthroscopic shoulder surgery. Female patients who were taking OCPs at the time of surgery were identified, and a control group consisting of female patients who were not taking OCPs was formed. These groups were propensity matched in a 1:1 fashion based on age, alcohol use, and comorbidities known to be associated with an increased risk of postoperative vascular thrombosis (obesity [body mass index $\geq$30 kg/m^2], diabetes, hypertension, hyperlipidemia, and smoking).[7] After matching, both groups were compared by the

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Ethical approval was not sought for the present study.

TABLE 1
Demographic Variables[a]

	Unmatched			Matched		
Variable	OCP	Control	*P* Value	OCP	Control	*P* Value
Total	924	26,365		890	890	
Age, y			<.001			.4
<20	116	204		108	108	
20-40	358	705		325	323	
41-60	434	7468		423	422	
>60	16	17,988		34	37	
Obesity	202	9388	<.001	185	185	>.99
Diabetes mellitus	118	8827	<.001	106	106	>.99
Hypertension	274	19,715	<.001	265	265	>.99
Hyperlipidemia	317	19,989	<.001	302	302	>.99
Smoking	90	4291	<.001	82	82	>.99
Charlson Comorbidity Index, mean	0.5 ± 1.1	1.5 ± 2.1	<.001	0.5 ± 1.1	0.6 ± 1.4	.1

[a]Data are shown as No. unless otherwise indicated. OCP, oral contraceptive pill.

Charlson Comorbidity Index (CCI) to ensure adequate matching.

The overall rate of diagnosed, symptomatic vascular thrombosis (number of patients with upper extremity DVT, lower extremity DVT, or PE) as well as individual rates of upper and lower extremity DVT and PE was assessed for patients taking OCPs and the control group within 90 days of arthroscopic shoulder surgery.[5] Vascular thrombosis was identified by ICD-9 and ICD-10 diagnosis codes for upper extremity DVT, lower extremity DVT, or PE. Patients who underwent vascular ultrasound within 90 days of the index procedure were also identified using CPT codes (93971, 93970, 93930, 93931, 93926, 93925). It should be noted that the indication for vascular ultrasound was unidentifiable within the database. It is possible that vascular ultrasound was performed for a reason unrelated to developing VTE secondary to arthroscopic shoulder surgery.

Statistical analysis was performed with Excel (Microsoft). Odds ratios (ORs) and 95% CIs of developing postoperative vascular complications were calculated with respect to the control group. Statistical comparisons of group demographics and rates of vascular thrombosis were performed using chi-square analysis. A Student *t* test was used to compare the CCI. Risk factors for DVT were assessed using multivariate binomial logistic regression analysis controlling for patient demographics and comorbidities, such as age, sex, obesity, diabetes, and smoking status using R Studio software version 1.0.143 (R Foundation for Statistical Computing). Matching for the control and OCP groups was also performed with R Studio software version 1.0.143. For all statistical comparisons, $P < .05$ was considered statistically significant.

RESULTS

A total of 57,727 patients underwent arthroscopic shoulder surgery from 2007 to 2016, of whom 26,365 patients (45.7%) were female. A total of 328 cases of vascular thrombosis (0.57%) occurred after arthroscopic shoulder surgery, which included 196 cases (0.34%) of PE. The rate of vascular thrombosis was not significantly different in male and female patients (n = 178 [0.57%] vs 150 [0.57%], respectively; $P > .99$). At the time of surgery, 924 female patients (3.5%) were taking OCPs. There was no difference in the incidence of vascular thrombosis in patients taking OCPs at the time of surgery versus female patients not taking OCPs (n = 2 [0.22%] vs 150 [0.57%], respectively; $P = .2$) . Patient age and comorbidities significantly differed in patients taking versus not taking OCPs ($P < .001$) (Table 1). After a 1:1 propensity match, there were 890 patients who were taking OCPs and 890 patients in the control group. There were no statistical differences between either group with respect to the age distribution and comorbidities (Table 1). Before matching, there was a statistical difference in the CCI between the OCP and control groups (0.5 vs 1.5, respectively; $P < .001$); however, after matching, there was no difference in the CCI (0.5 vs 0.6, respectively; $P = .1$).

TABLE 2
Independent Risk Factors for Vascular Thrombosis[a]

Variable	Odds Ratio (95% CI)	*P* Value
Hypertension	**2.00 (1.57-2.28)**	**<.001**
Obesity	**1.43 (1.14-1.64)**	**.002**
Diabetes	1.23 (0.98-1.55)	.08
Contraceptive use	0.52 (0.15-0.78)	.22
Alcohol use	1.36 (0.87-2.10)	.42
Hyperlipidemia	1.16 (1.01-1.33)	.43
Smoking	1.10 (0.82-1.30)	.52

[a]Bolded values indicate statistical significance ($P < .05$).

On multivariate regression, obesity (OR, 1.43 [95% CI, 1.14-1.64]; $P = .002$) and hypertension (OR, 2.00 [95% CI, 1.57-2.28]; $P < .001$) were independent risk factors for vascular thrombosis among all female patients undergoing arthroscopic shoulder surgery (Table 2). However, diabetes ($P = .08$), smoking ($P = .52$), alcohol use ($P = .42$),

TABLE 3
Statistical Comparisons (*P* Values) of Vascular Complications by Procedure[a]

Complication	Labral Repair	SLAP Repair	Rotator Cuff Repair	Glenohumeral Debridement
Pulmonary embolism	.3	—	—	.3
Deep vein thrombosis	—	.3	.6	.3

[a]SLAP, superior labral tear from anterior to posterior.

hyperlipidemia ($P = .43$), age ($P > .99$), and OCP use ($P = .22$) were not risk factors for vascular thrombosis. After the 1:1 propensity match, there was no statistical difference in the total number of vascular thrombosis cases within 90 days of the index procedure in female patients who took OCPs versus the control group (n = 2 [0.22%] vs 5 [0.56%], respectively; $P = .2$). There were no cases of upper extremity DVT in the study population. Within each type of arthroscopic shoulder procedure, there was no statistical difference in the rate of developing overall vascular thrombosis, lower extremity DVT, or PE ($P > .05$) (Table 3). After operative management, 17 patients (1.9%) who were taking OCPs underwent vascular ultrasound within 90 days of surgery, while 23 control patients (2.6%) underwent vascular ultrasound during the same time period ($P = .3$). Of these, a single patient taking OCPs (5.9%) and 3 control patients (13.0%) were subsequently diagnosed with vascular thrombosis after ultrasound, respectively.

DISCUSSION

The principal finding of our study was that female patients taking OCPs at the time of arthroscopic shoulder surgery were not at an increased risk for a thromboembolic event in comparison with female patients not taking OCPs. Our data support retaining the null hypothesis. Secondary findings include a low rate of symptomatic VTE regardless of the risk factors analyzed in this study. We identified obesity and hypertension as independent risk factors for thromboembolic events. Additional medical risk factors analyzed in this study were not independent risk factors for VTE.

The risk of VTE after shoulder surgery is low, with rates quoted between 0% and 5.7%[6,15,25]; for arthroscopic shoulder surgery, the rates of symptomatic VTE are extremely low, ranging from 0.01% to 0.38%.[3,6,11,15,20,25] In this investigation, the rate of VTE after arthroscopic shoulder surgery (0.57%) was higher than what has been previously reported. OCP use is widespread and relevant to the patient population that may undergo arthroscopic shoulder surgery.[10,23] According to data collected from the multicenter RECOS Registry, OCP use was not an independent risk factor for developing VTE after shoulder surgery (including arthroplasty and other open procedures); however, their total study population was 1366 patients, with only 17 patients taking OCPs at the time of surgery.[10] While our findings are in agreement with those of Imberti et al,[10] our study is more appropriately powered to detect a difference and further supports the conclusion that OCPs do not increase the DVT risk. A lack of association between VTE and OCPs in arthroscopic shoulder surgery is in agreement with more recent data regarding simple arthroscopic knee surgery, which did not find the use of OCPs and hormone replacement therapy to be significant independent predictors of VTE after arthroscopic knee surgery.[14] OCP use appears to carry no additional risk for VTE in orthopaedic arthroscopic surgery.

While OCPs were not associated with an increased risk for VTE, our study did identify that obesity and hypertension were increased risk factors for the development of VTE in female patients. Hypertension and obesity are known risk factors for thrombus formation.[18] These risk factors may promote venous stasis and endothelial damage, which may lead to clot formation. Schick et al[20] analyzed more than 15,000 shoulder arthroscopic procedures performed in the United States from 2002 to 2011, and no statistically significant risk factors were identified in the 22 cases of reported VTE. A larger systematic review of more than 92,000 patients identified that diabetes mellitus, rheumatoid arthritis, and ischemic heart disease were all risk factors for developing DVT.[6] Jameson et al[11] found a similar risk associated with diabetes, an increased CCI, and ischemic heart disease. We did not find an association with ischemic heart disease in our group of female patients; however, the mean age was lower in our analysis, which may have influenced the results. Medication use, such as OCPs, was not evaluated in the prior analyses.

While the incidence of symptomatic VTE after arthroscopic shoulder surgery is low, a prospective evaluation of asymptomatic VTE reported an incidence of 5.7% in 175 patients who underwent arthroscopic shoulder surgery in the beach-chair position.[25] The authors highlighted that DVT was found 1 to 2 days postoperatively by ultrasound, despite the use of intraoperative mechanical prophylaxis (in the form of sequential compression devices). Only 1 patient in this study became transiently symptomatic, which is congruent not only with the rate identified in the present study but also consistent with the previously reported range of 0.01% to 0.38%.[11,15,25] The benefits of chemical prophylaxis for VTE in arthroscopic shoulder surgery are not clear, despite the reported findings of asymptomatic VTE. A clear consensus statement on VTE prophylaxis in arthroscopic shoulder surgery has not been issued.[10] Our findings suggest patients taking OCPs are at no increased risk for VTE and should be treated with the surgeon's standard prophylaxis protocol.

The present study has several important limitations. The data are extracted from a large private-payer database and do not account for all surgical procedures performed in the United States during the study period; despite this limitation, the study group is a large sample size, which is useful for detecting small differences. Because this investigation utilizes a large private-payer database, it is subject to selection bias, as high-risk groups may be excluded from this study. Insurance status may be an indirect indication of higher social or financial status, which may portend better outcomes and fewer complications. The results of this

investigation are dependent on accurate coding on behalf of the physicians and their practices. The incidence of inaccurate coding has not been assessed in this database. The large sample also includes a large number of surgeons with regional variations in patient selection and surgical practices, which helps support a broader application of the study's conclusions. There is also variation in the practice of VTE prophylaxis, which may affect the incidence of VTE.

The results of this investigation are also reliant on how vigorously physicians screen for VTE. The true rate of VTE may be higher, as it is difficult to quantify the rate of asymptomatic VTE. Pharmacy insurance claims were used to determine which patients were prescribed OCPs, which are more reliable than self-reported OCP use and an audit of electronic prescriptions (which may not be filled); despite the advantage of identifying paid prescriptions filled, we operated under the assumption that patients who paid for OCPs were actually taking them as prescribed at the time of surgery. One additional limitation is that we did not examine the use of intrauterine devices for contraceptive use. While these devices are popular, they are not reported to be associated with an increased risk for DVT because they act through a different mechanism. It is possible that the type of OCP may influence the development of VTE; however, this variable was not assessed in the current investigation. Previous reports did not find an association with oral contraceptive and DVT.[24]

Patients with a history of DVT or PE were excluded from the analysis. These patients were previously identified to have an increased risk of developing a thrombolic event after both arthroscopic shoulder and knee procedures.[14] Lateral positioning, use of mechanical prophylaxis, and operative time are factors that have been previously shown to influence the rate of VTE development; however, these factors were unable to be assessed and controlled for in this investigation.[12] Furthermore, the findings may be limited because of the possibility that this investigation may be underpowered to identify statistical differences.

CONCLUSION

OCP use at the time of arthroscopic shoulder surgery is not associated with an increased risk of VTE. Obesity and hypertension are associated with a greater risk for thrombolic events in female patients, although the risk remains very low. Our findings suggest that patients taking OCPs should be managed according to the surgeon's standard prophylaxis protocol for arthroscopic shoulder surgery.

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