

COMMITTEE OPINION

s of enous hro boe bo s A ong sers of Drosp renone Conta n ng Ora Contracept ve P s

ABSTRACT: Although the risk of venous thromboembolism is increased among oral contraceptive users compared with nonusers who are not pregnant and not taking hormones, and some data have suggested that use of drospirenone-containing pills has a higher risk of venous thromboembolism, this risk is still very low and is much lower than the risk of venous thromboembolism during pregnancy and the immediate postpartum period. When prescribing any oral contraceptive, clinicians should consider a woman's risk factors for venous thromboembolism and refer to the **U.S. Medical Eligibility Criteria for Contraceptive Use** issued by the Centers for Disease Control and Prevention. Patient education materials, including product labeling, should place information regarding oral contraceptive use and venous thromboembolism risks in context by also providing information about overall venous thromboembolism risks during pregnancy and the postpartum period. Decisions regarding choice of oral contraceptive should be left to clinicians and their patients, taking into account the possible minimally increased risk of venous thromboembolism, patient preference, and available alternatives.

 $n \neq ora$ ontra pt v s, Cs t, at onta $n \neq ro$, , av su : st / a, .; rrs o v noust, ro o asso at / w t, t, us o Cs t, at onta n / rosp r. non o par wt, Cst, at onta not, rpro st ns. su, as vonor str , , wo ar stu s, on ar Dut, as - ontro stu/, an/ on o, ort stu/, ro D n ar \ a so r port / n r as / r s s o v nous t, ro o os wt, us o rosprnon, ontann Cs o par / w t, vonor str , onta n n · Cs , . . . How v r. t, s stu/ s, a/s v ra t o oo a tat ons, su, as pot nt a s ass, at on o v nous os an t urat on o us o t na quat ontro o on oun n var a s, an pot n ta nor aton an / t ton as s. \ D sp t t s tat ons., t s oo a. paus to ons / r an $n \ r \ as \ / \ r \ s \ o_{\prime} \ o \ p \ at \ ons \ _{\prime} \ ro$ v nous t ro os w t, t, us o / rosp r non , onta n n $^{\circ}$ Cs as o par / wt ot r pro st n onta n n · Cs a. nvo v / w t, ostas s., a/n 'to a ras noa ua t, ror, t ant nrao. ort o / prop rt s o / rosp r non ou / n turn a/ to

n r as / rs o v nous t ro o o s w t t us o / rosp r non onta n n · Cs, /

Atrrv wn t / atant s asw asot rstu/. s,t, Foo an Dru A n strat on FDA ssu a Drug Safety Communication n w, $t on u \neq t$, at us o rosp r non onta n n · Cs a. wt, a, ; rrs o oo otst, an ot, rpro stn, onta n n · Cs B aus t, stu/ s// not prov/ ons st nt st at s o t o parat v r s o oo ots tw n / rosp r non, onta n n · Cs an / ot, r pro st n onta n n · Cs an aus t stu s a to a ount or portant pat nt , ara t r st s, su , as s o n status an o o ass n , t at a n u n . a, tt rs o oo/ prsr n an/ FDA was una to on u ausa t

wonst/as-ontrostu/status/int/
tatsan/int/Kn/ona/ata assoun/t,
rs o non ata / opat/v noust, ro o os to
two to t, r t s, ; ra on n w urr nt us rs
o / rosp r non / onta n n · Cs o par / wt, us rs o
vonor · str / onta n n · Cs / in / In or at on r ar /
n · C us was as rta n / ro a p, ar a / ata as

r or / ro / ru · a s n on stu · . A an / ro a r s ar , / ata as n t, ot, r stu · . A / nt , / pat nts w t, v nous t, ro o o s , a / to , av r v / on ; t r ant oa u at on t, rap. In on trast, a G r an as - ontro stu · oun / s arrs so on r / v nous t, ro o o s tw n us rs o / rosp r non onta n n · Cs an / vonor · str · onta n n · Cs . A t, ou ; so nown pot nt a on oun / rs w r / nt / an a / ust / or n t, s stu / s, as - ontro stu / s r a n sus pt to on oun / n · . un nown var a s, s t on as, an / a : nost r · rra as, a on ot, r · a tors

tv. vauat / t, rsso ar ovasuar opatonsa on os nwusrso Cs, nun wo nwo wrtan rosprnon ontann Cs, wo wratv. osrv or os wo an ars, Casso vnoustro o os wrvr / wt

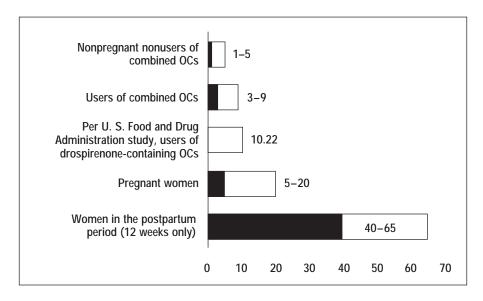


Fig. 1. Likelihood of developing a blood clot (number of women with a blood clot per 10,000 women-years). Abbreviation: OC indicates oral contraceptives. Adapted from Food and Drug Administration. FDA drug safety communication: updated information about the risk of blood clots in women taking birth control pills containing drospirenone. Silver Spring (MD): FDA; 2012. Available at: http://www.fda.gov/DrugS/DrugSafety/ucm299305. Retrieved July 5, 2012. Additional information from Food and Drug Administration. Combined hormonal contraceptives (CHCs) and the risk of cardiovascular disease endpoints. Silver Spring (MD): FDA; 2011. Available at: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM277384.pdf. Retrieved July 5, 2012. ^

oo'sts Co tt on G, n oo' rat a st,

 Decisions regarding the choice of OC should be left to n ans an t, r pat nts, ta n nto a ount t, o own a tors

to o os nnwusrsorosprnon
ontann Cs o par wt usrso o n
Cs / //// wo an ars o par wt
at nt pr r n
Ava a at rnat v s

- Women should have a wide range of contraceptive opt ons, n u n rosp r non, onta n n Cs
- If a patient is using a drospirenone-containing OC an s to rat n t, r n, t, r s no n to s ont nut at C
- When prescribing any OC, dinicians should consider a wollans riscolar a torsor vinous tyrological solutions, and riscolar to type U.S. Medical Eligibility Criteria for Contraceptive Use
- Patient education materials including product label n; s, ou / pa n or at on r ar/n rssov noust, ro o os n ont t a so prov/n n or at on a out ov ra v noust, ro o os rssan/v noust, r

Box, H gh s Factors for enous hro boe bos n sers of Co b ned Ora Contracept ves ^

- · Smoking and age 35 years or older
- Less than 21 days postpartum or 21–42 days postpartum with other risk factors
- · Major surgery with prolonged immobilization
- History of deep vein thrombosis or pulmonary embolism
- Hereditary thrombophilia (including antiphospholipid syndrome)
- Inflammatory bowel disease with active or extensive disease, surgery, immobilization, conticosteroid use, vitamin deficiencies, or fluid depletion
- Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies

*Oral contraceptive use in women with these conditions is classified as U.S. Medical Eligibility Oriteria Category 3 (theoretical or proven risks usually outweigh the advantages of using the method) or Category 4 (condition that represents an unacceptable health risk if the contraceptive method is used).

Data from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 Centers for Disease Control and Prevention (CDC). MVM/R RecommRep 2010;59(RR-4):1-86[Pub/Ved] [Full Text] and Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 revised recommendations for the use of contraceptive methods during the postpartum period. Centers for Disease Control and Prevention (CDC). MVM/R Morb Mortal Wkly Rep 2011;60878-83 [Pub/Ved] [Full Text]

References

- - van Groot, st K, r n , ro o o s asso at wt t n w ontra pt v Yas n B, J // , , , u , , Fu , t, ^
 - ona ontra pt on and rs o v nous t ro o o os nat ona o ow up study. By J // // // // Lu // Fu t //
 - van H. a a. A. H. r. orst F. . an n rou
 J. Do n CJ. os n aa F. ., v nous t ro ot rs
 o ora ontra pt v s. tso o stro n os an pro s
 to n t p r su ts o t EGA as ontro stu. B. J
- apro Dnr J s o v nous t ro o o s a on us rs o ora ontra pays ar v wo twor nt. pu s stu s J Fa ann pro Hat Car //
- Du ros E, B rt, aut A, rs, a, Faussat A, or a J, A arwa K, ta A ost ron o s, ostas s v a upr u at on o t, prot n C r ptor n, u an vas u ar n ot, u Bo, Bop, s s Co un //
- Foo an Dru A n strat on FDA ru sa t o u n at on up at n or at on a out; rs o oo ots n wo n ta n rt, ontro p s onta n n rosp r non vr prn; D FDA / Ava a at, ttp.

 www.a ov Dru s Dru a t u / tr v
- Ju., H rnan K s o non ata v noust ro o o s n wo n us n ora ontra pt v s onta n n rosp r non o par w t wo n us n ora ontra pt v s onta n n vonor str as ontro stu us n

- J, a r A s s o t ro o o s n wo n ta n t n stra o rosp r non an ot r ora on tra pt v s st t G, n o //, .../, -, u .../, Obstetrics & Gynecology. ^
- Dnr J. Bar n, ur K. o, nr . . , rs o v nous t ro o os nus rs o a rosp r non onta nn ora ontra pt v w t, a . . a r · n - r su ts ro t IMA. C tu., a stratt Frt tr //
- Dn r J, n, D, Butt ann M, Bar n, u r K
 E tv n ss o ora ontra ptv p s n a ar
 o, ort o parn proston an r n st t
 G, n o / ..., / u Cobstetrics &
 Gynecology ^
- Foo an Dru'A n strat on Con n, or ona on trapt v s, CHCs and t, rs o ar ovas u ar s as n ponts v r prn; D FDA / Ava a at ttp. www.na ov.own oa s Dru s Dru a t. C.